

[Volume III, Appx00621 – Appx00966]

Nos. 22-1972, -1973, -1975, -1976

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,

Appellant,

v.

APPLE INC.,

Appellee.

APPEAL FROM THE PATENT TRIAL AND APPEAL BOARD
CASE NOS. IPR2020-01713, IPR2020-01716, IPR2020-01733, IPR2020-01737

JOINT APPENDIX

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(12) **United States Patent**
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(54) **MULTI-STREAM DATA COLLECTION
SYSTEM FOR NONINVASIVE
MEASUREMENT OF BLOOD
CONSTITUENTS**

(58) **Field of Classification Search**

CPC A61B 5/1455; A61B 5/14551; A61B
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(Continued)

(71) Applicant: **Masimo Corporation**, Irvine, CA (US)

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(*) Notice: Subject to any disclaimer, the term of this
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U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

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A61B 5/145 (2006.01)

(52) **U.S. Cl.**

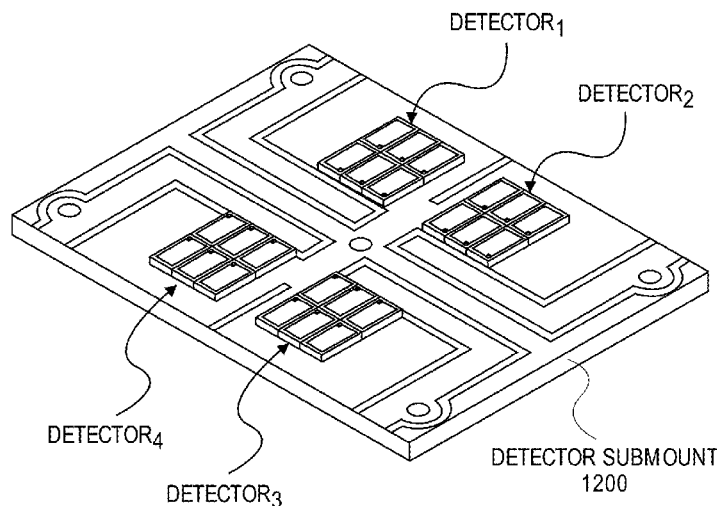
CPC **A61B 5/1455** (2013.01); **A61B 5/14532**
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(57)

ABSTRACT

The present disclosure relates to noninvasive methods,
devices, and systems for measuring various blood constitu-
ents or analytes, such as glucose. In an embodiment, a light
source comprises LEDs and super-luminescent LEDs. The
light source emits light at at least wavelengths of about 1610
nm, about 1640 nm, and about 1665 nm. In an embodiment,
the detector comprises a plurality of photodetectors arranged
in a special geometry comprising one of a substantially
linear substantially equal spaced geometry, a substantially
linear substantially non-equal spaced geometry, and a sub-
stantially grid geometry.

27 Claims, 65 Drawing Sheets



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Related U.S. Application Data

- continuation of application No. 16/534,949, filed on Aug. 7, 2019, now Pat. No. 10,588,553, which is a continuation of application No. 16/409,515, filed on May 10, 2019, now Pat. No. 10,376,191, which is a continuation of application No. 16/261,326, filed on Jan. 29, 2019, now Pat. No. 10,292,628, which is a continuation of application No. 16/212,537, filed on Dec. 6, 2018, now Pat. No. 10,258,266, which is a continuation of application No. 14/981,290, filed on Dec. 28, 2015, now Pat. No. 10,335,068, which is a continuation of application No. 12/829,352, filed on Jul. 1, 2010, now Pat. No. 9,277,880, which is a continuation of application No. 12/534,827, filed on Aug. 3, 2009, now abandoned, and a continuation-in-part of application No. 12/497,528, filed on Jul. 2, 2009, now Pat. No. 8,577,431, which is a continuation-in-part of application No. 29/323,408, filed on Aug. 25, 2008, now Pat. No. Des. 606,659, and a continuation-in-part of application No. 29/323,409, filed on Aug. 25, 2008, now Pat. No. Des. 621,516, said application No. 12/829,352 is a continuation-in-part of application No. 12/497,523, filed on Jul. 2, 2009, now Pat. No. 8,437,825, which is a continuation-in-part of application No. 29/323,408, and a continuation-in-part of application No. 29/323,409.
- (60) Provisional application No. 61/086,060, filed on Aug. 4, 2008, provisional application No. 61/086,108, filed on Aug. 4, 2008, provisional application No. 61/086,063, filed on Aug. 4, 2008, provisional application No. 61/086,057, filed on Aug. 4, 2008, provisional application No. 61/091,732, filed on Aug. 25, 2008, provisional application No. 61/078,228, filed on Jul. 3, 2008, provisional application No. 61/078,207, filed on Jul. 3, 2008.
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- (58) **Field of Classification Search**
CPC ... *A61B 5/6826*; *A61B 5/6816*; *A61B 5/6829*; *A61B 5/6838*; *A61B 2562/00*; *A61B 2562/04*; *A61B 2562/046*; *A61B 2562/06*; *A61B 2562/063*; *A61B 2562/066*
See application file for complete search history.
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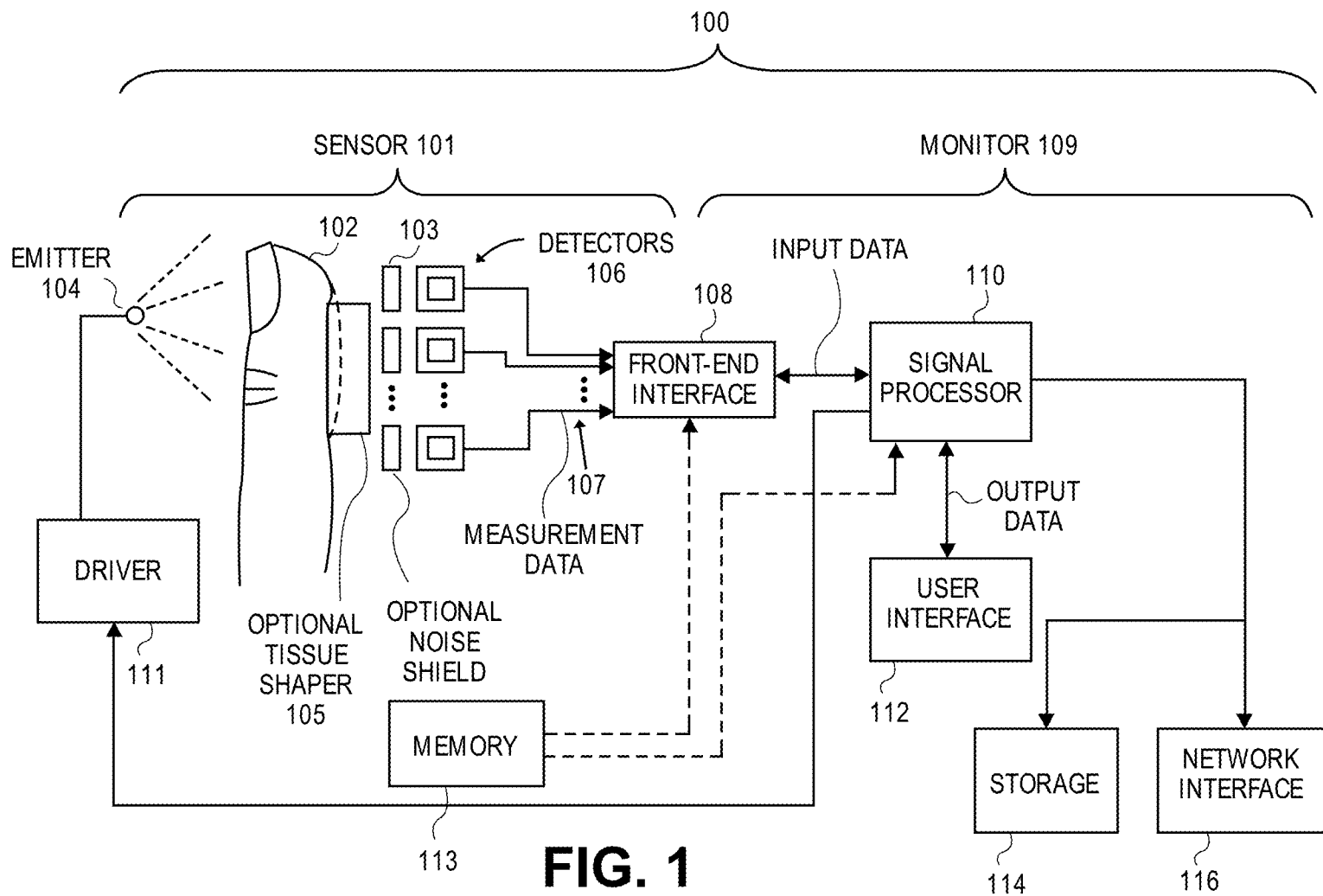


FIG. 1

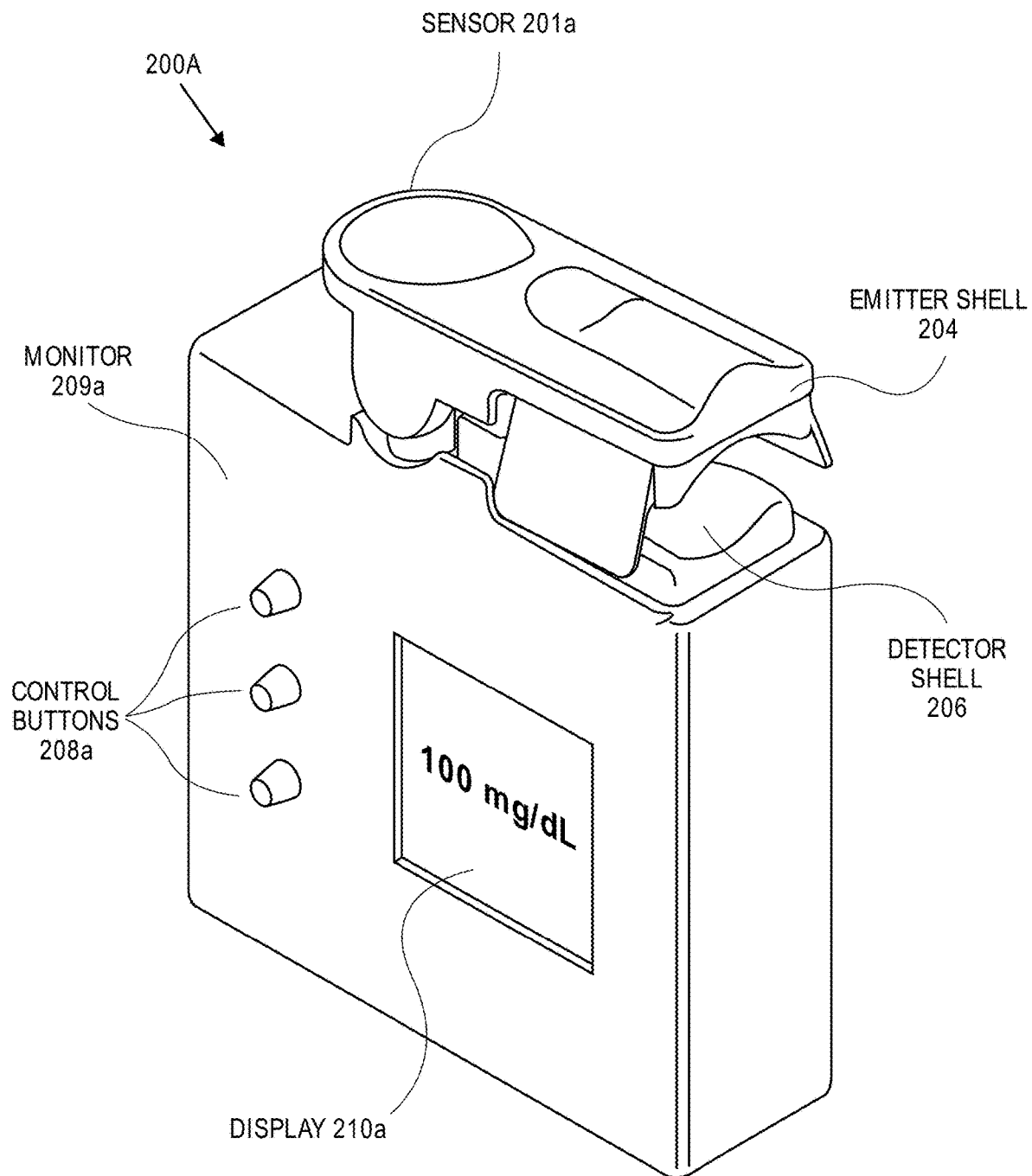
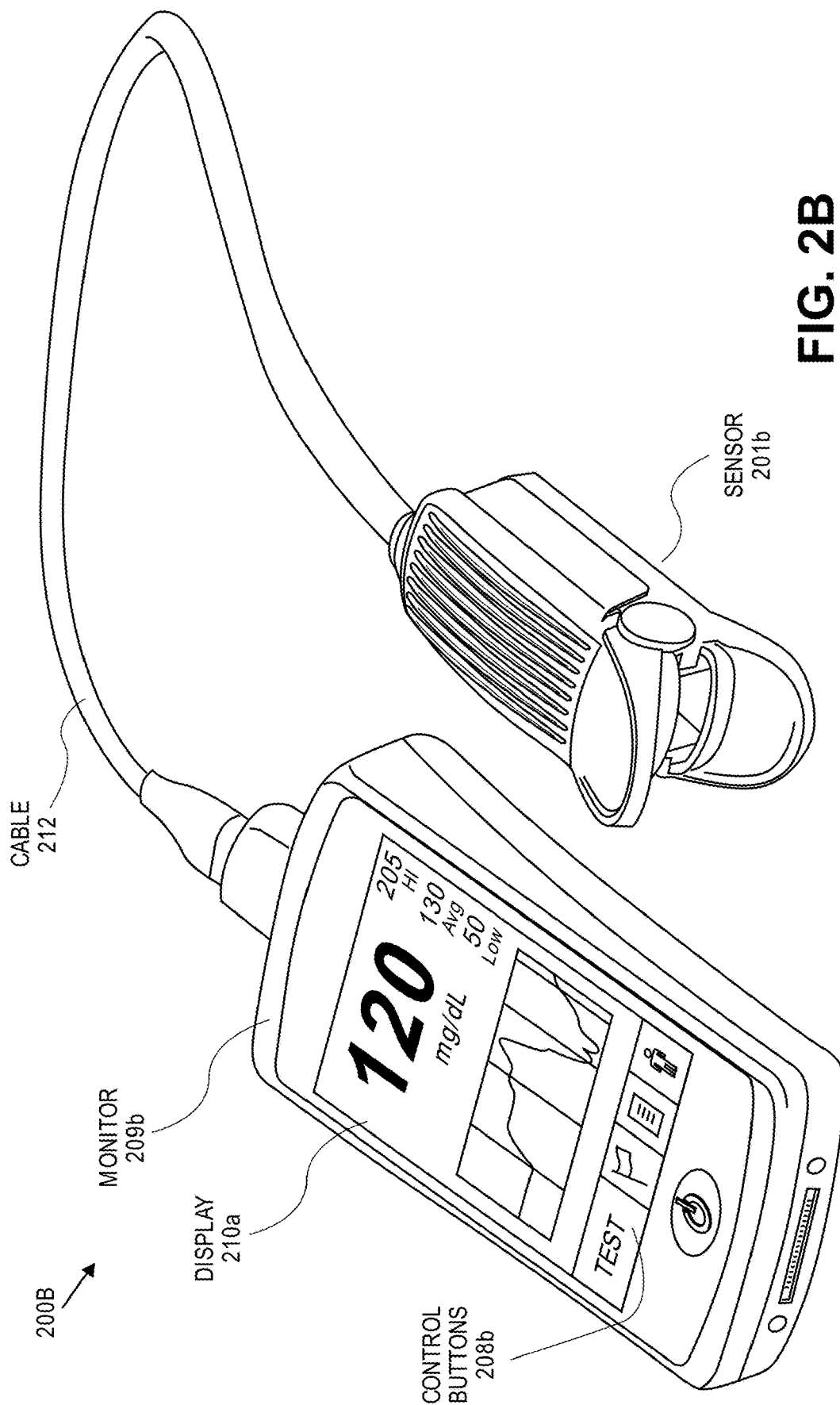


FIG. 2A



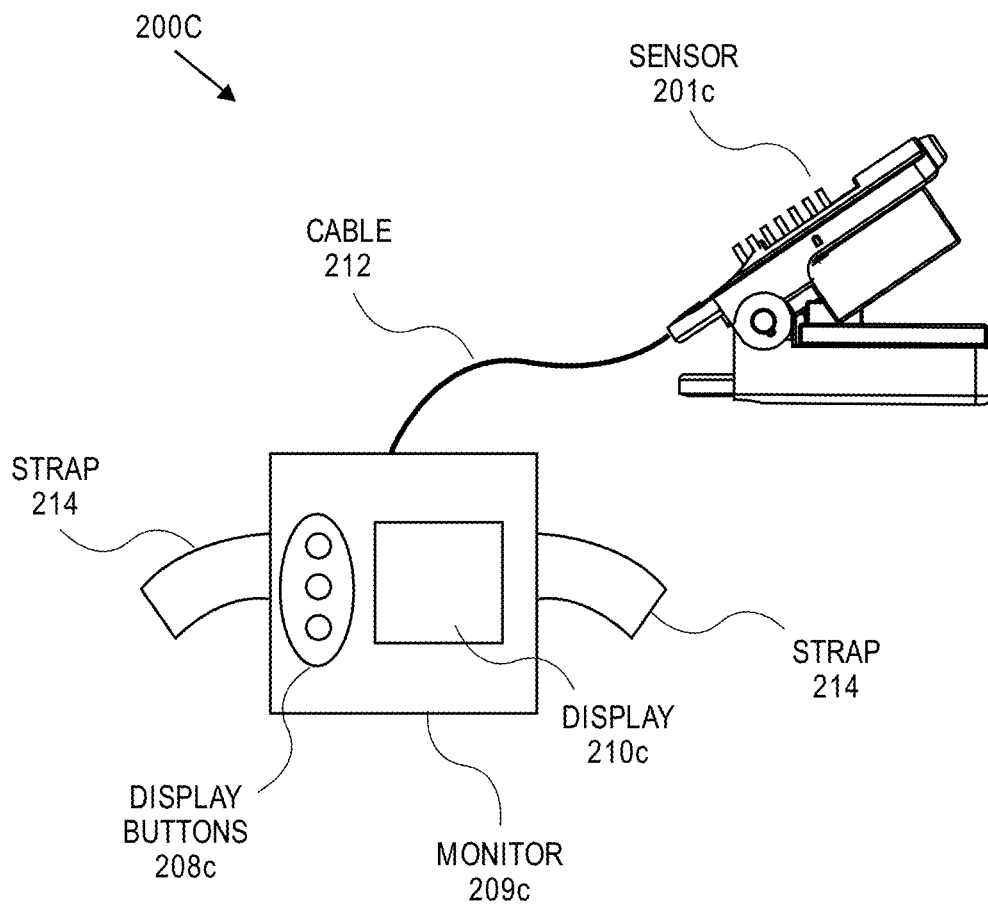


FIG. 2C

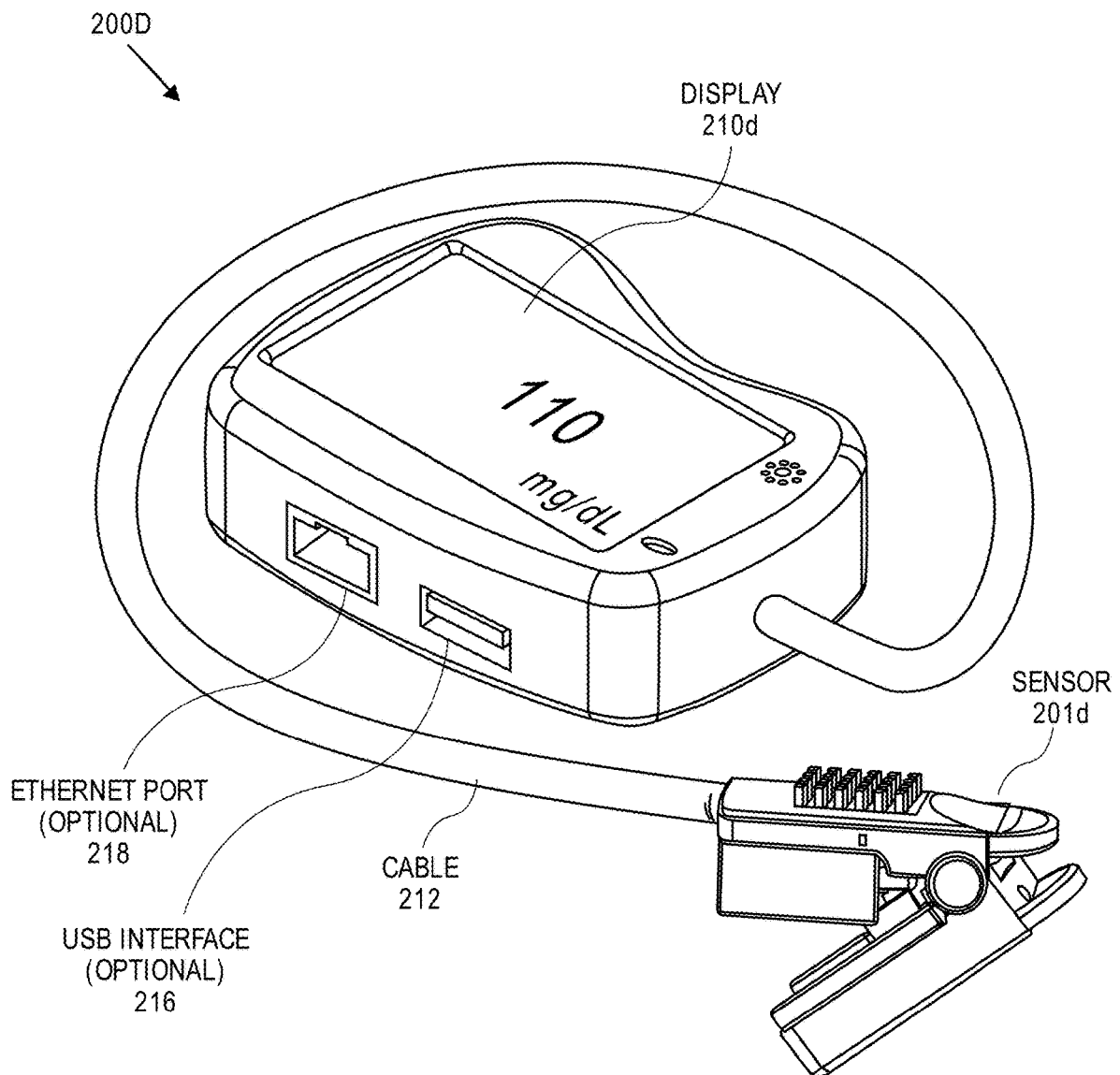


FIG. 2D

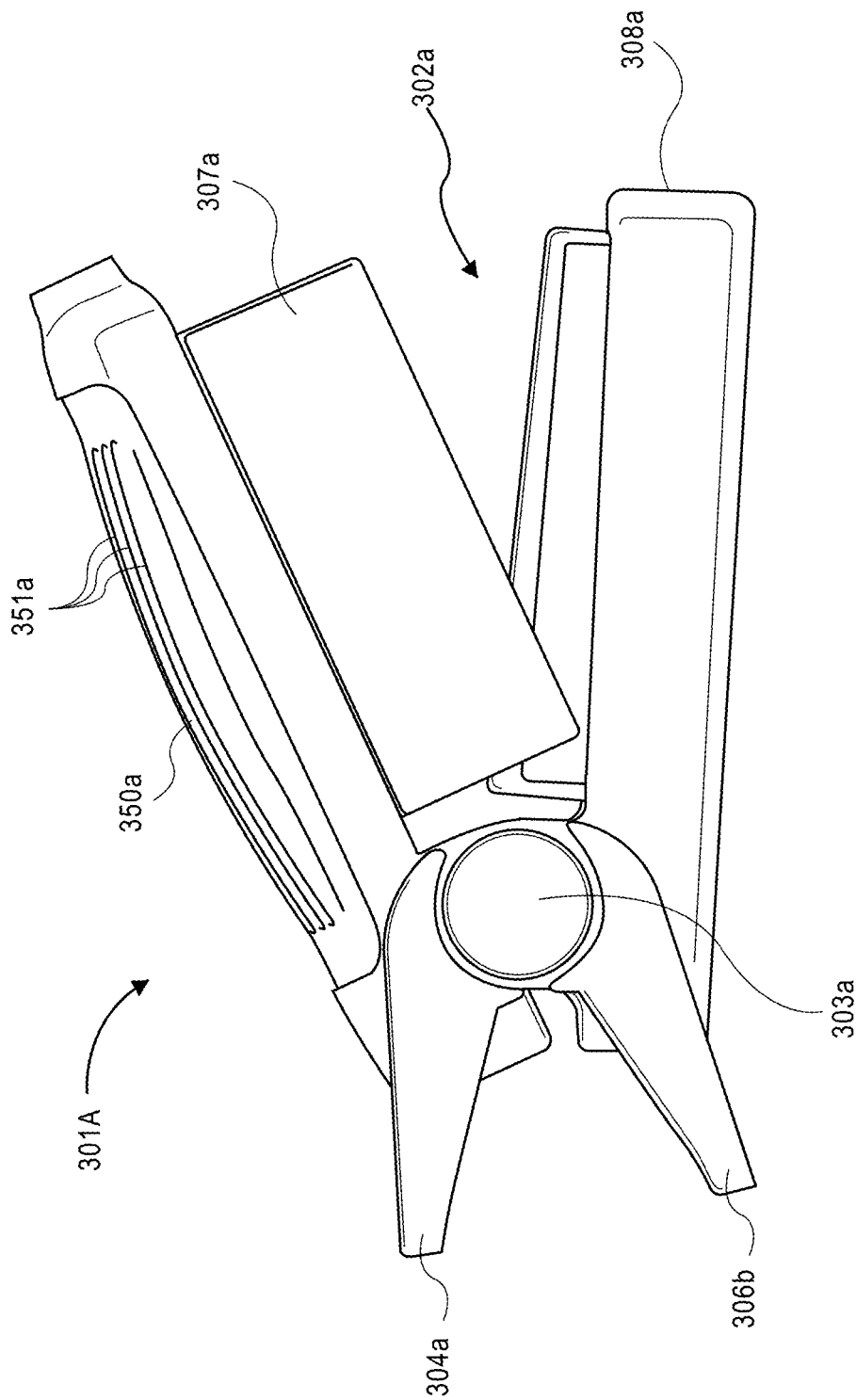


FIG. 3A

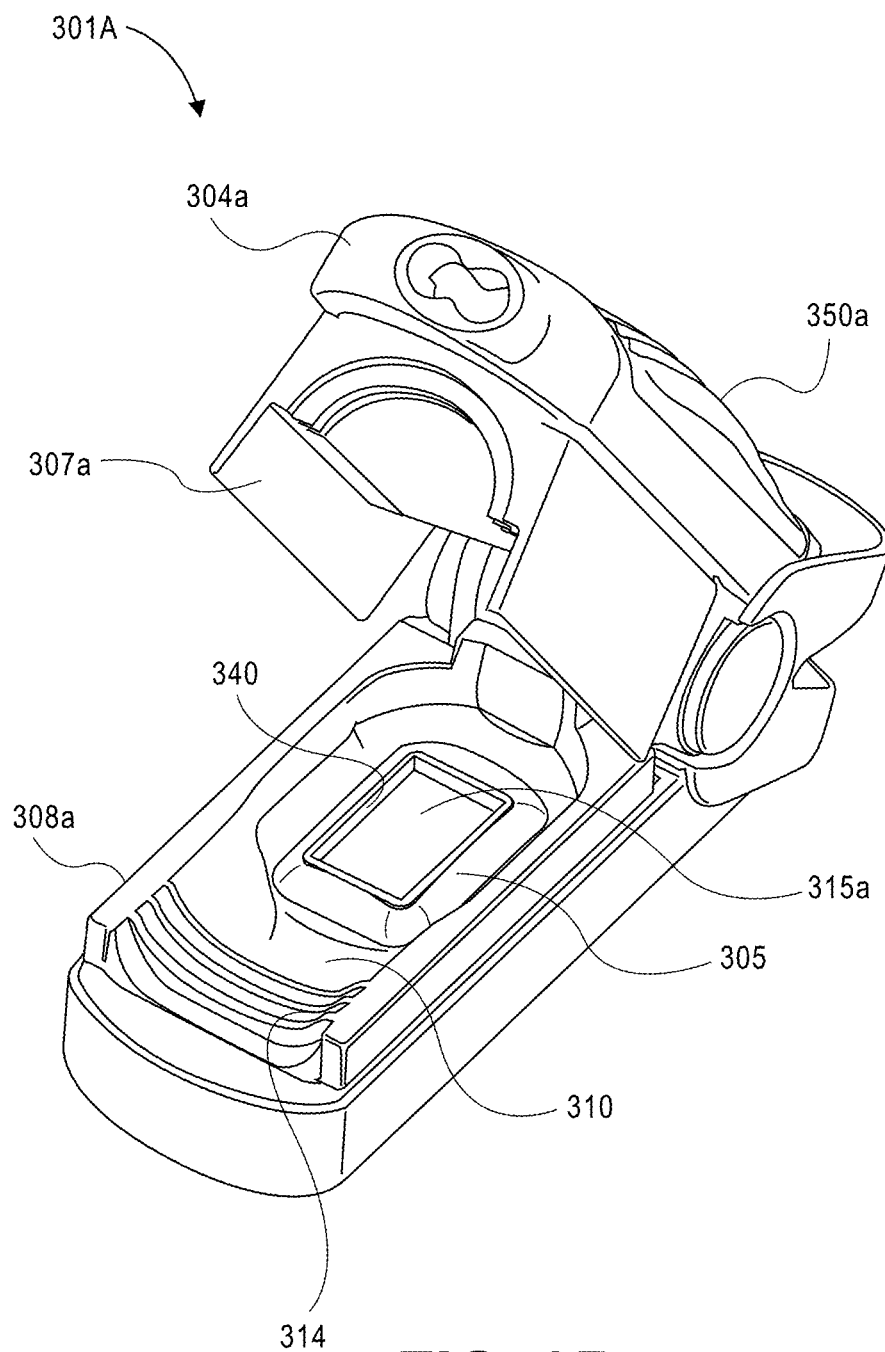


FIG. 3B

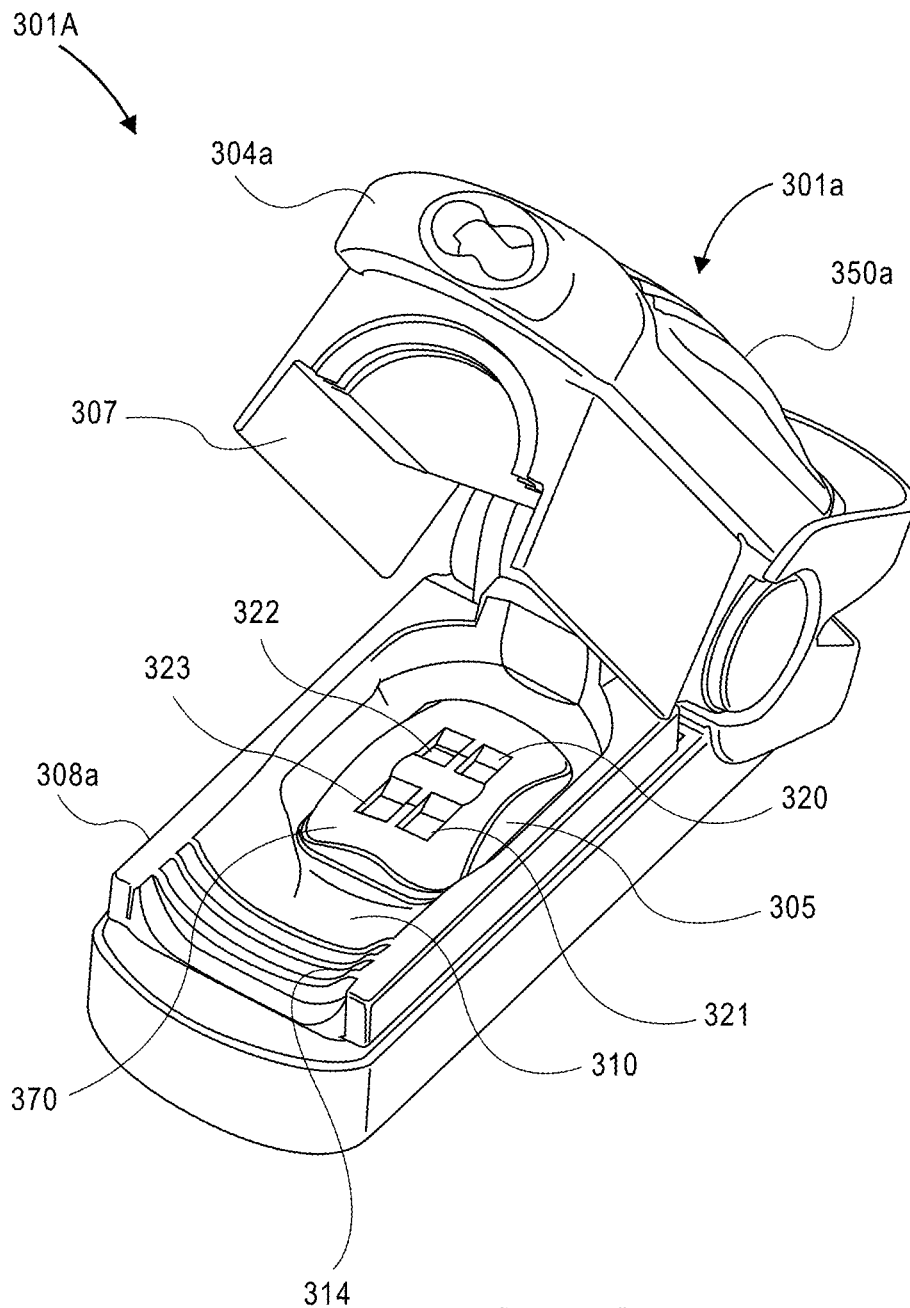


FIG. 3C

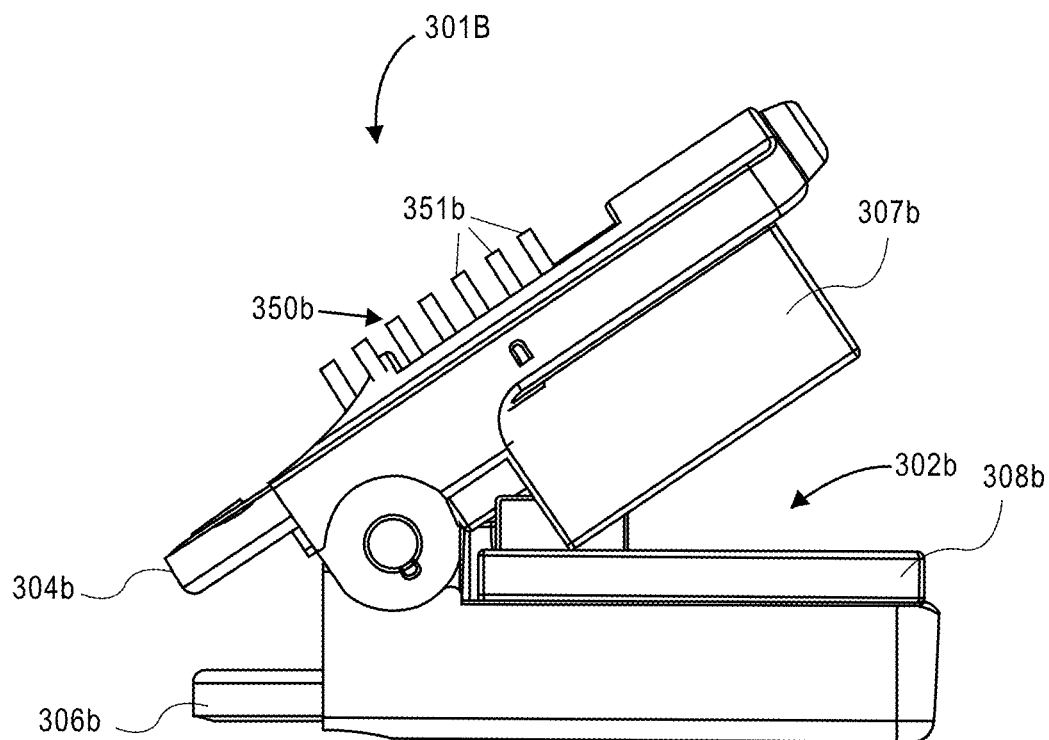


FIG. 3D

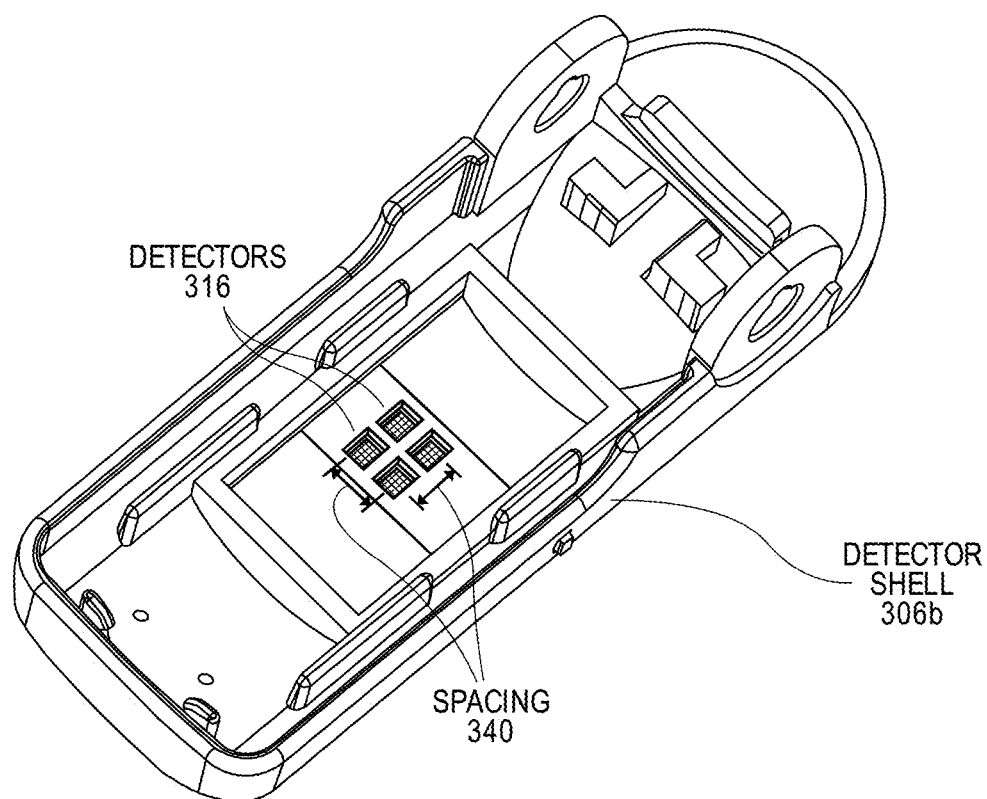


FIG. 3E

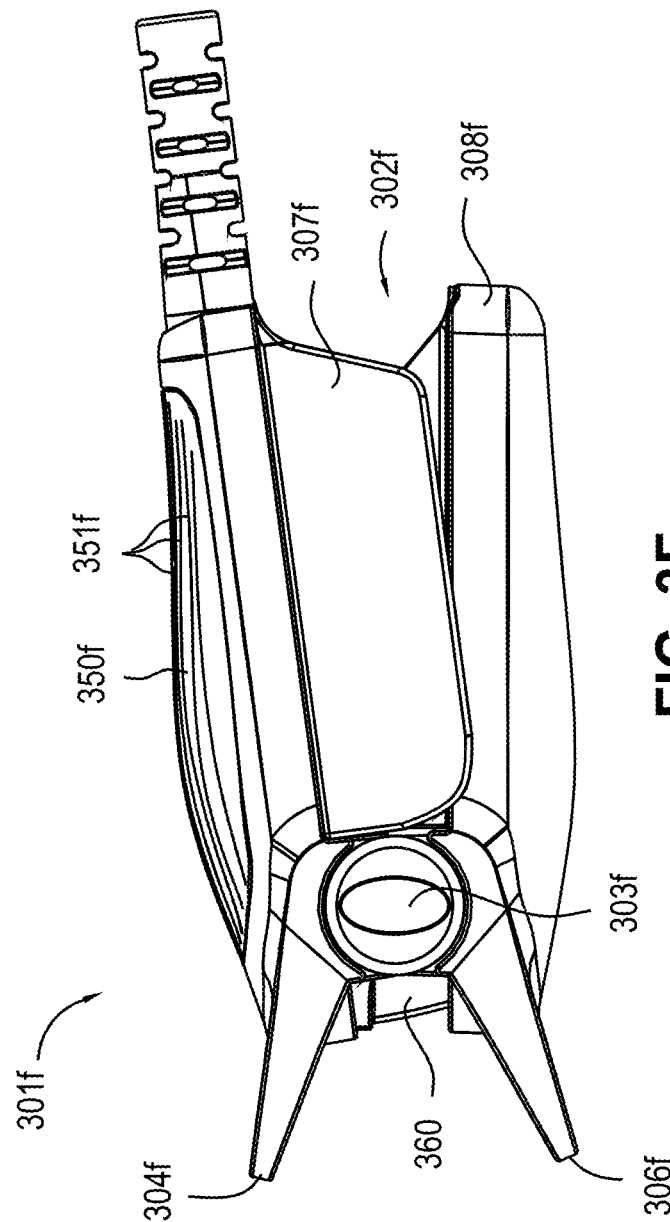


FIG. 3F

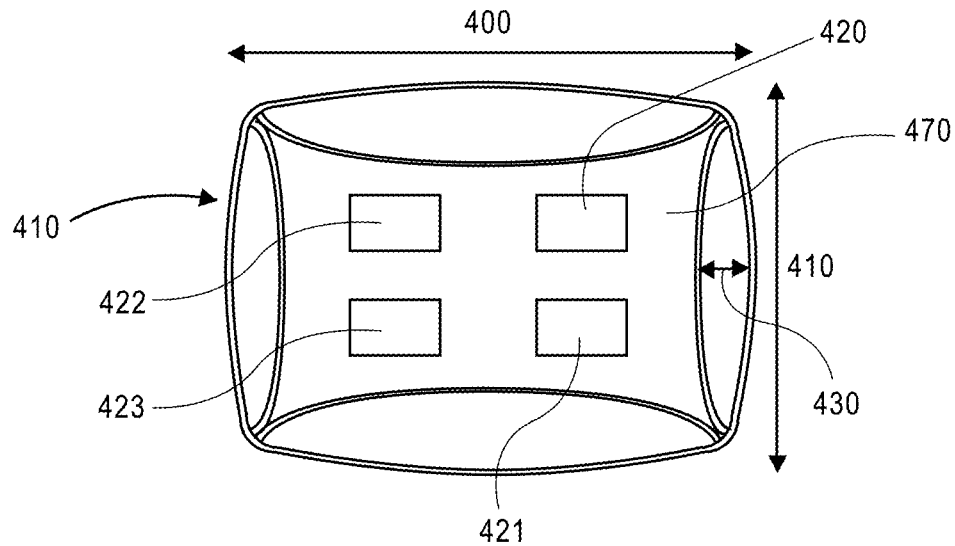


FIG. 4A

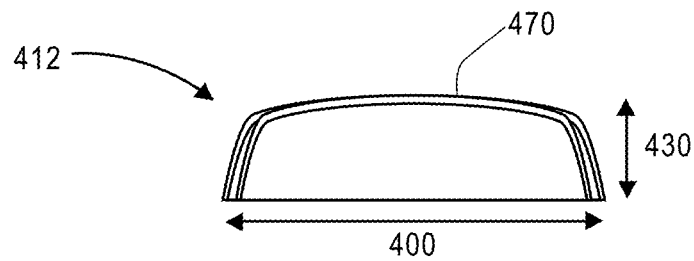


FIG. 4B

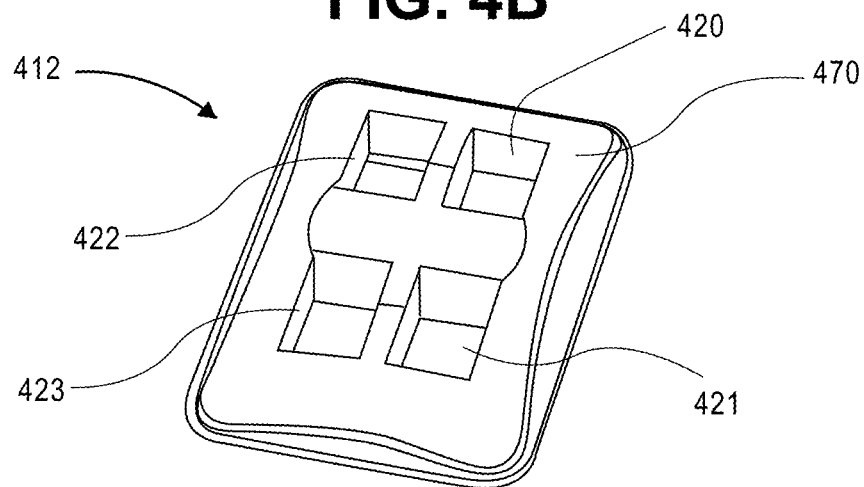


FIG. 4C

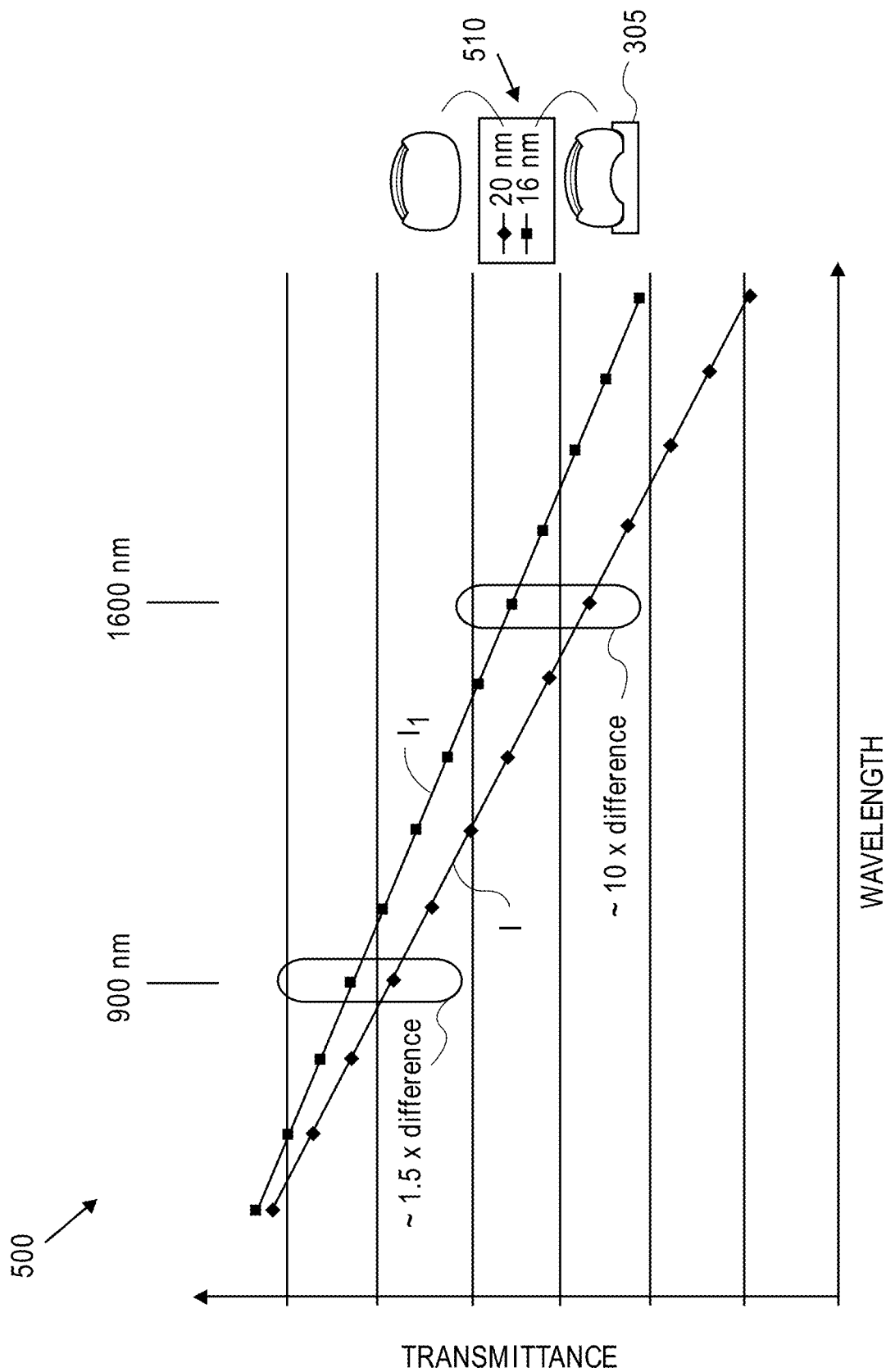


FIG. 5

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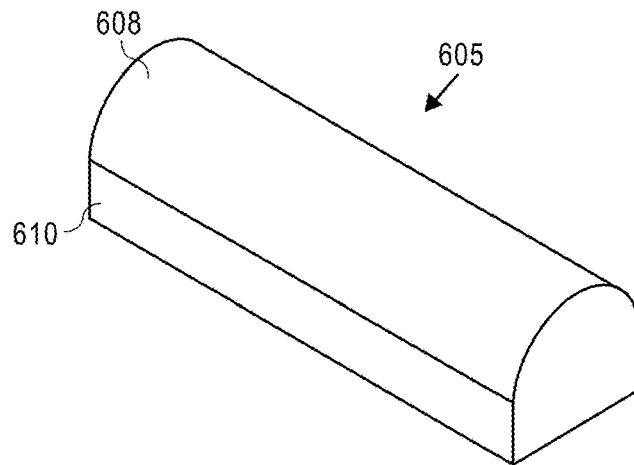


FIG. 6A

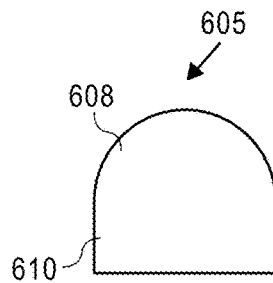


FIG. 6B

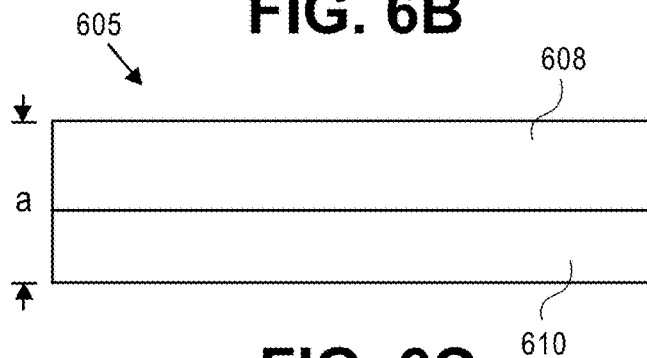


FIG. 6C



FIG. 6D

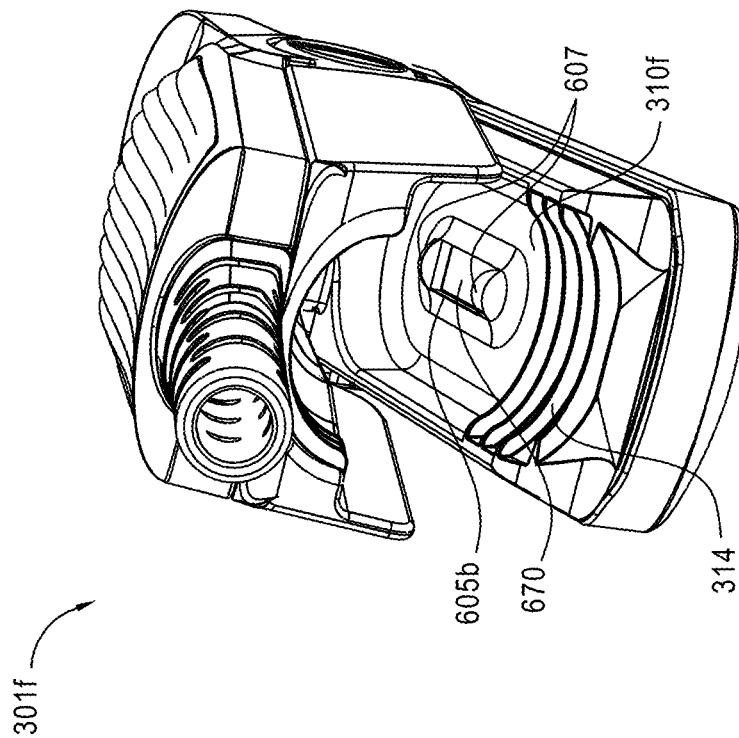


FIG. 6E

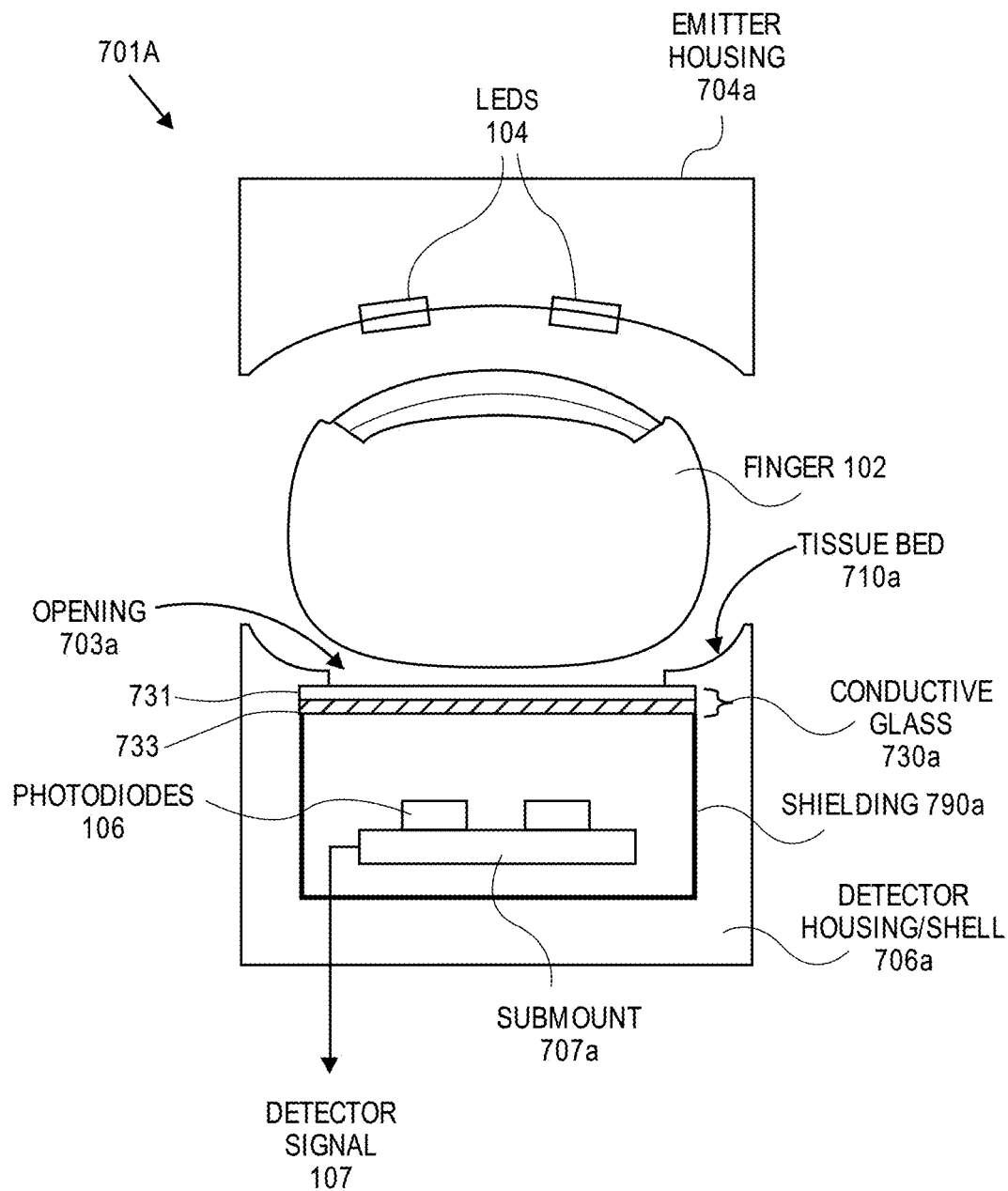


FIG. 7A

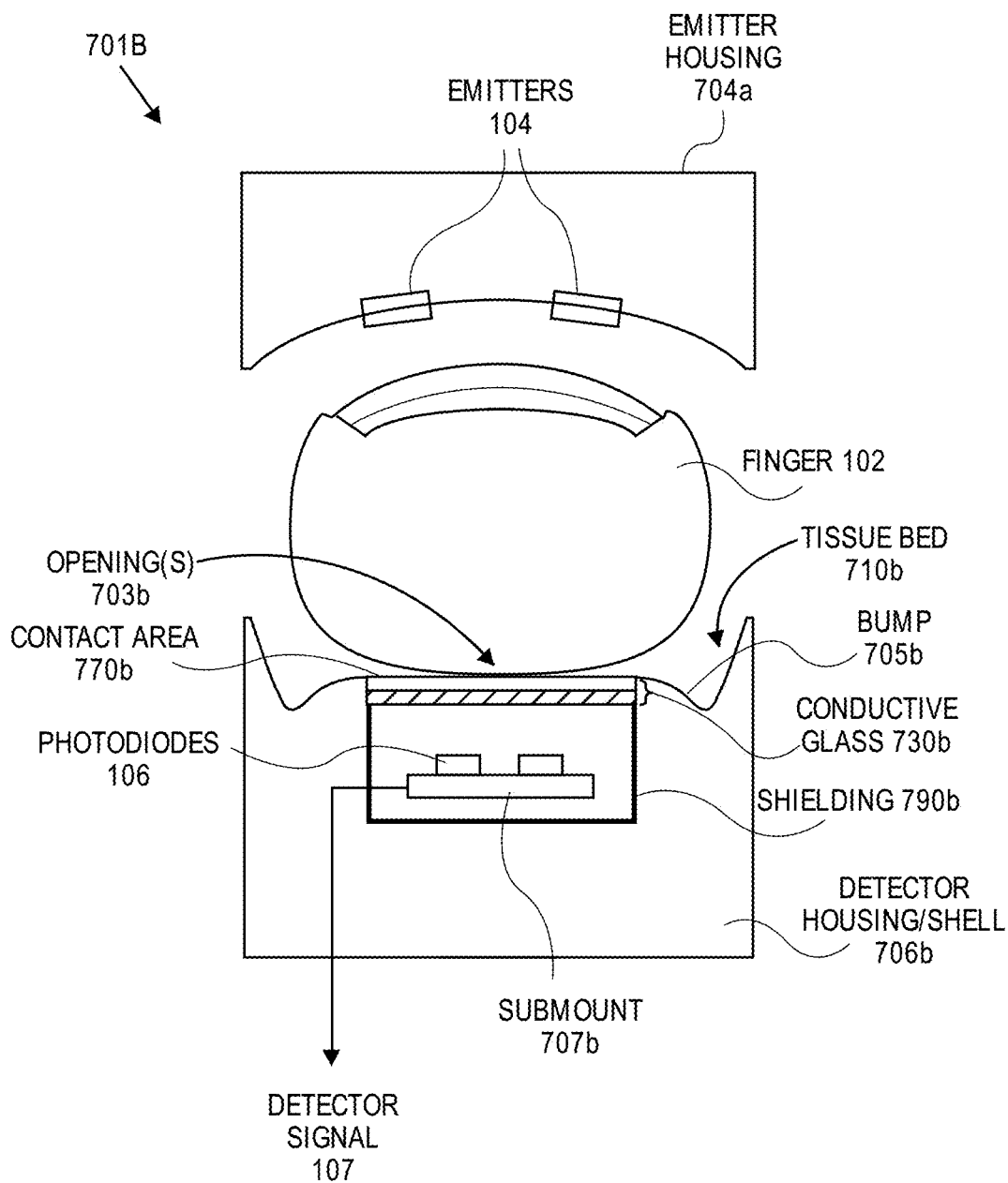


FIG. 7B

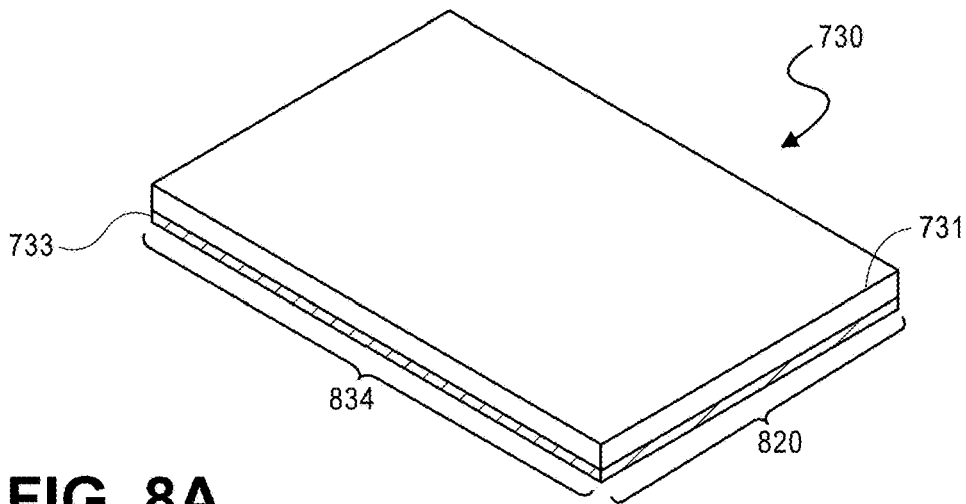


FIG. 8A

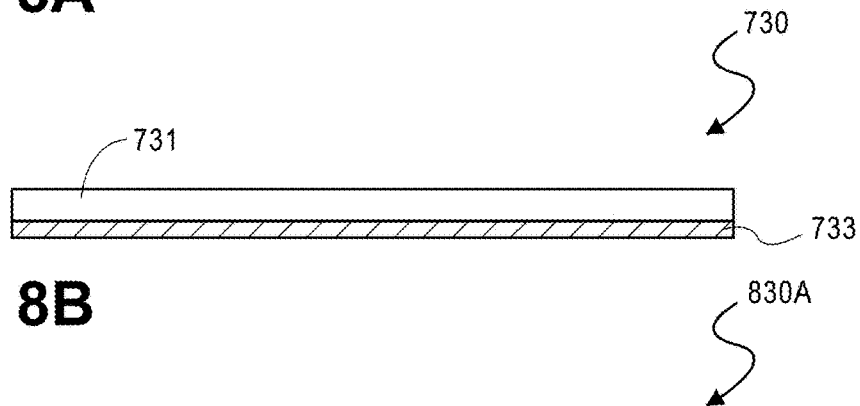


FIG. 8B

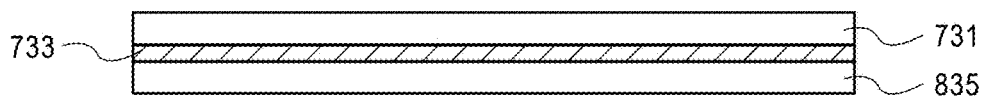


FIG. 8C

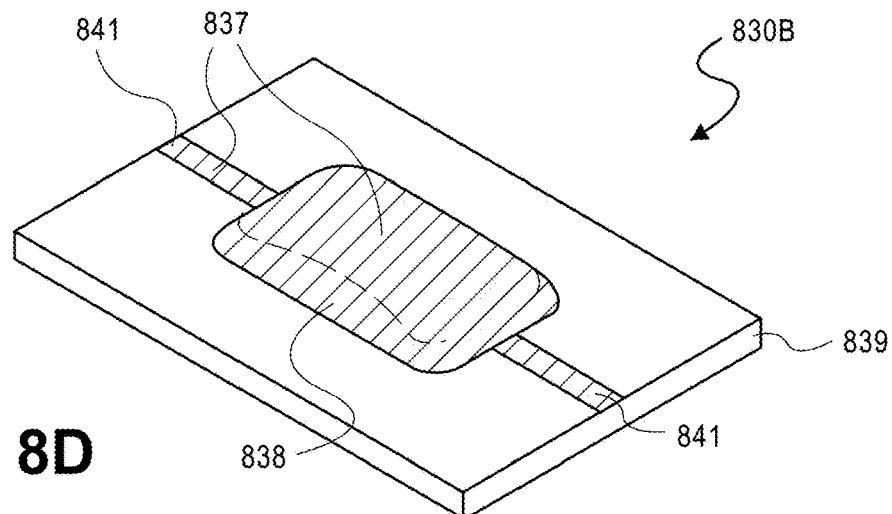


FIG. 8D

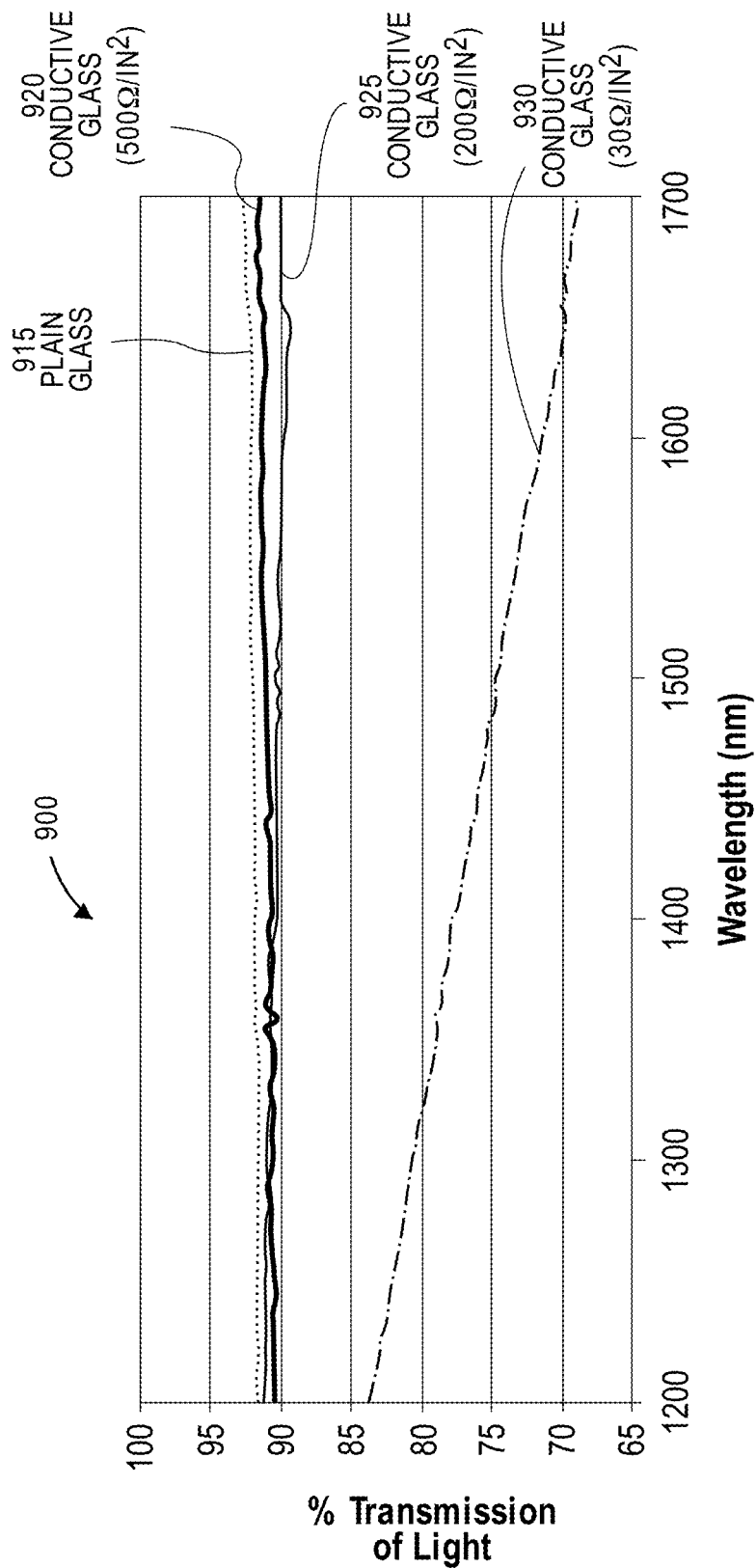


FIG. 9

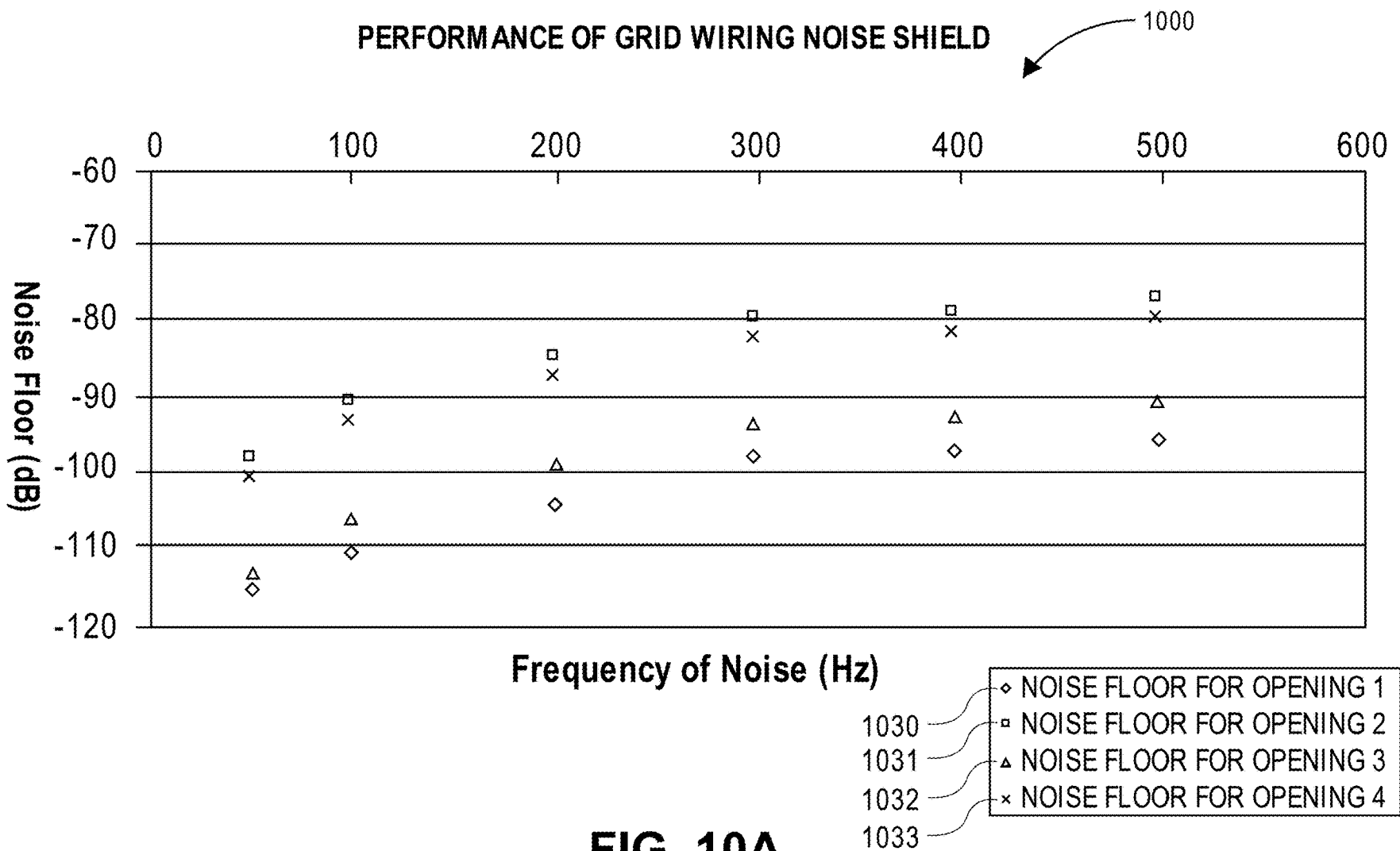


FIG. 10A

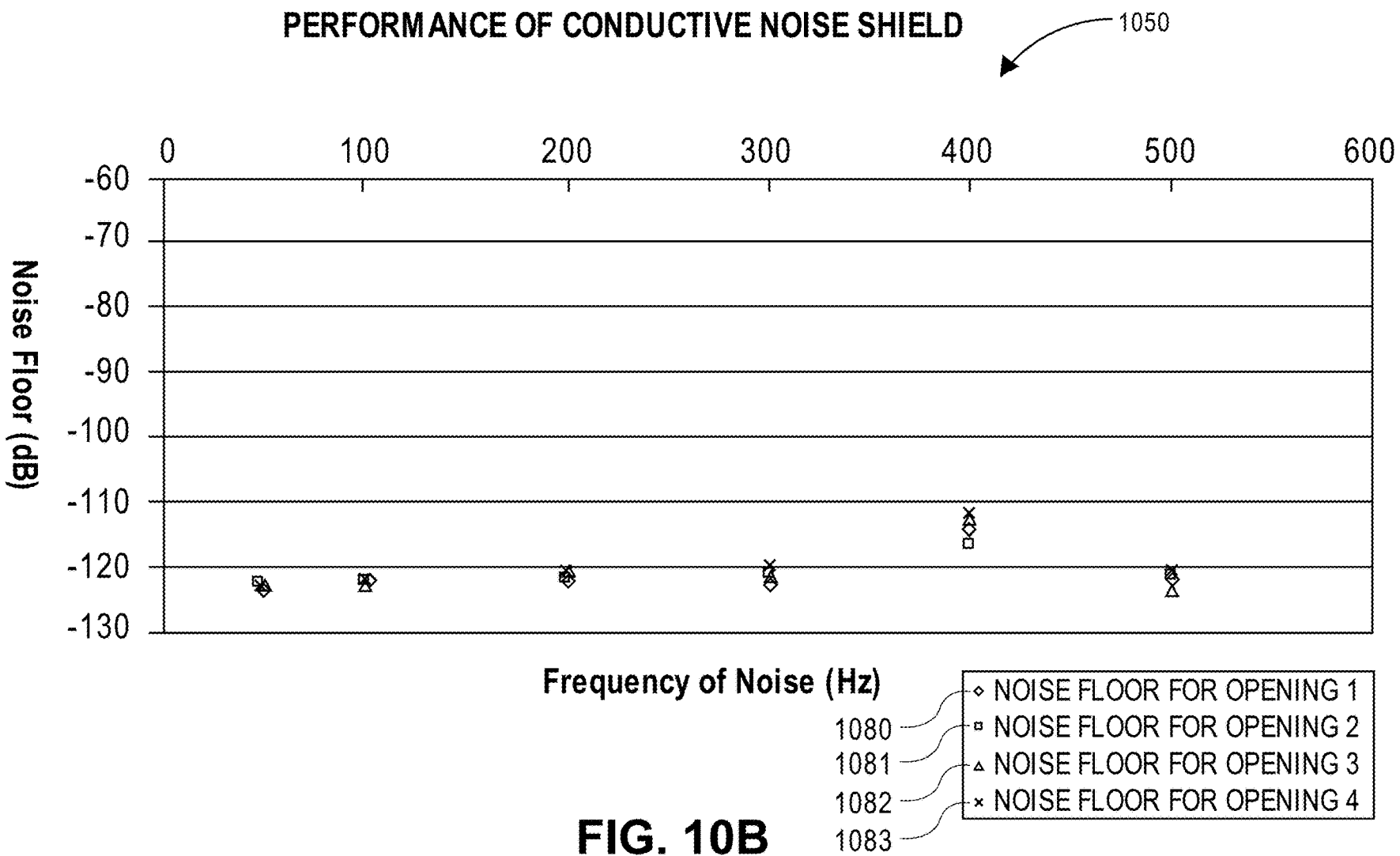
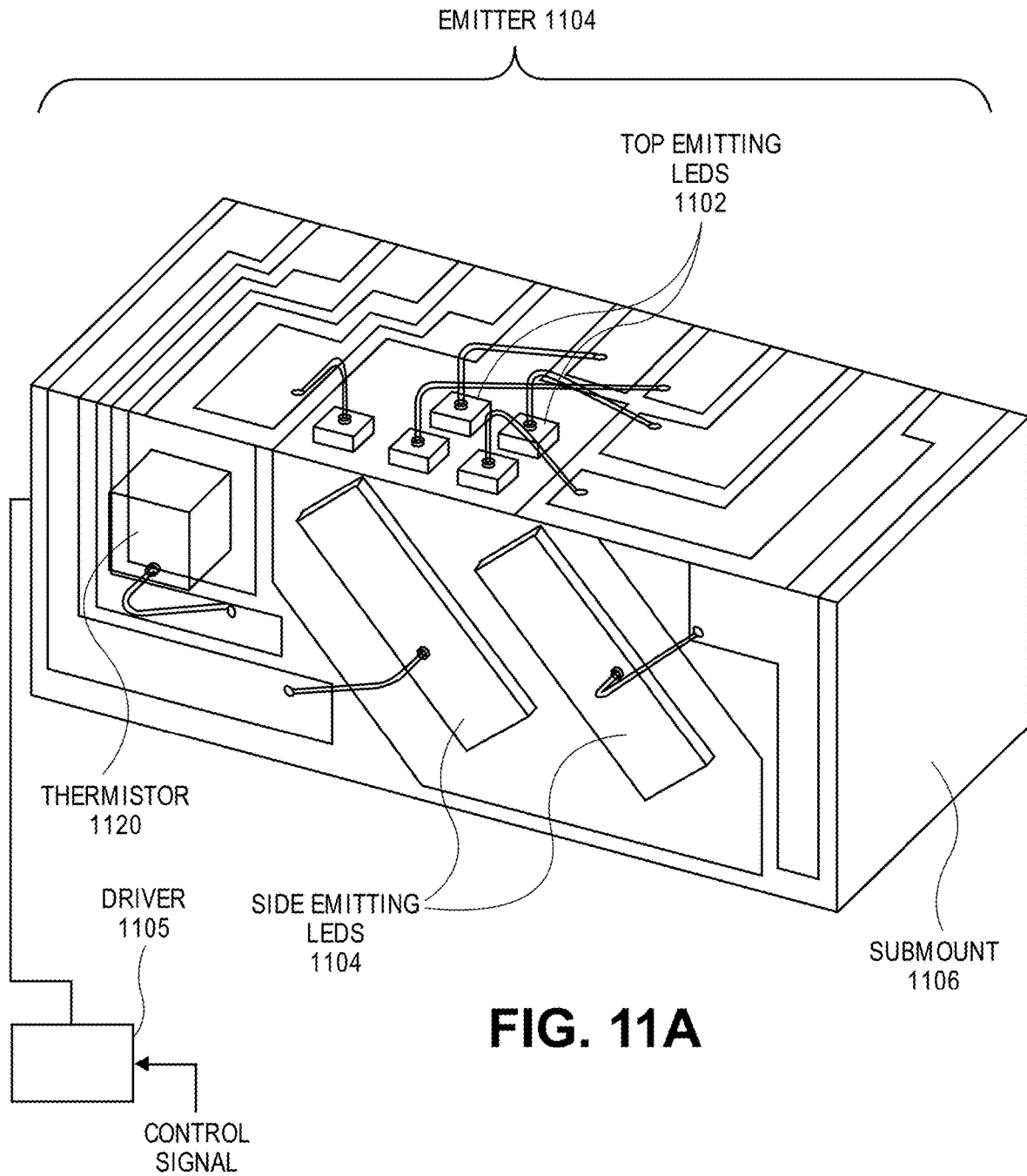


FIG. 10B



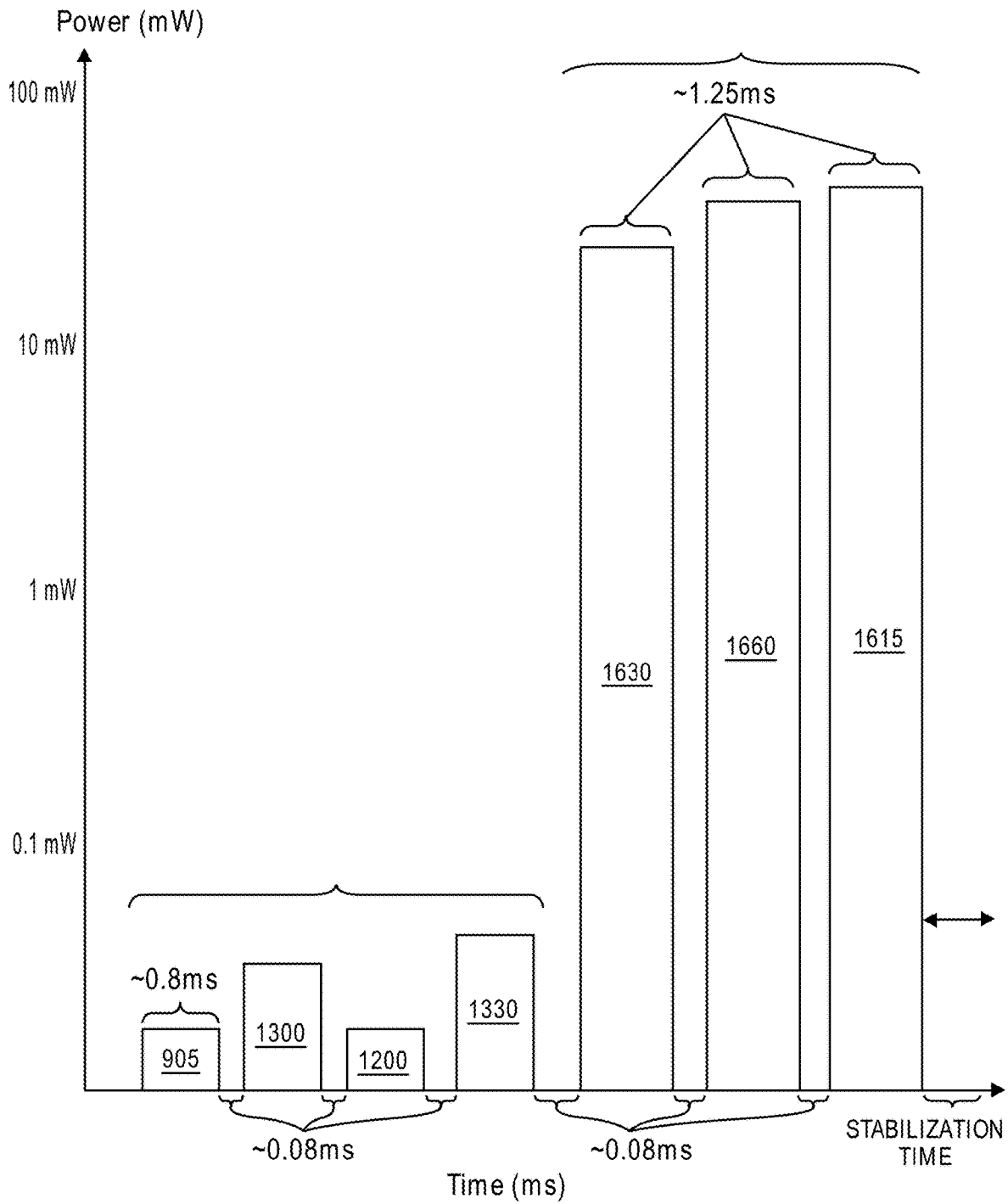


FIG. 11B

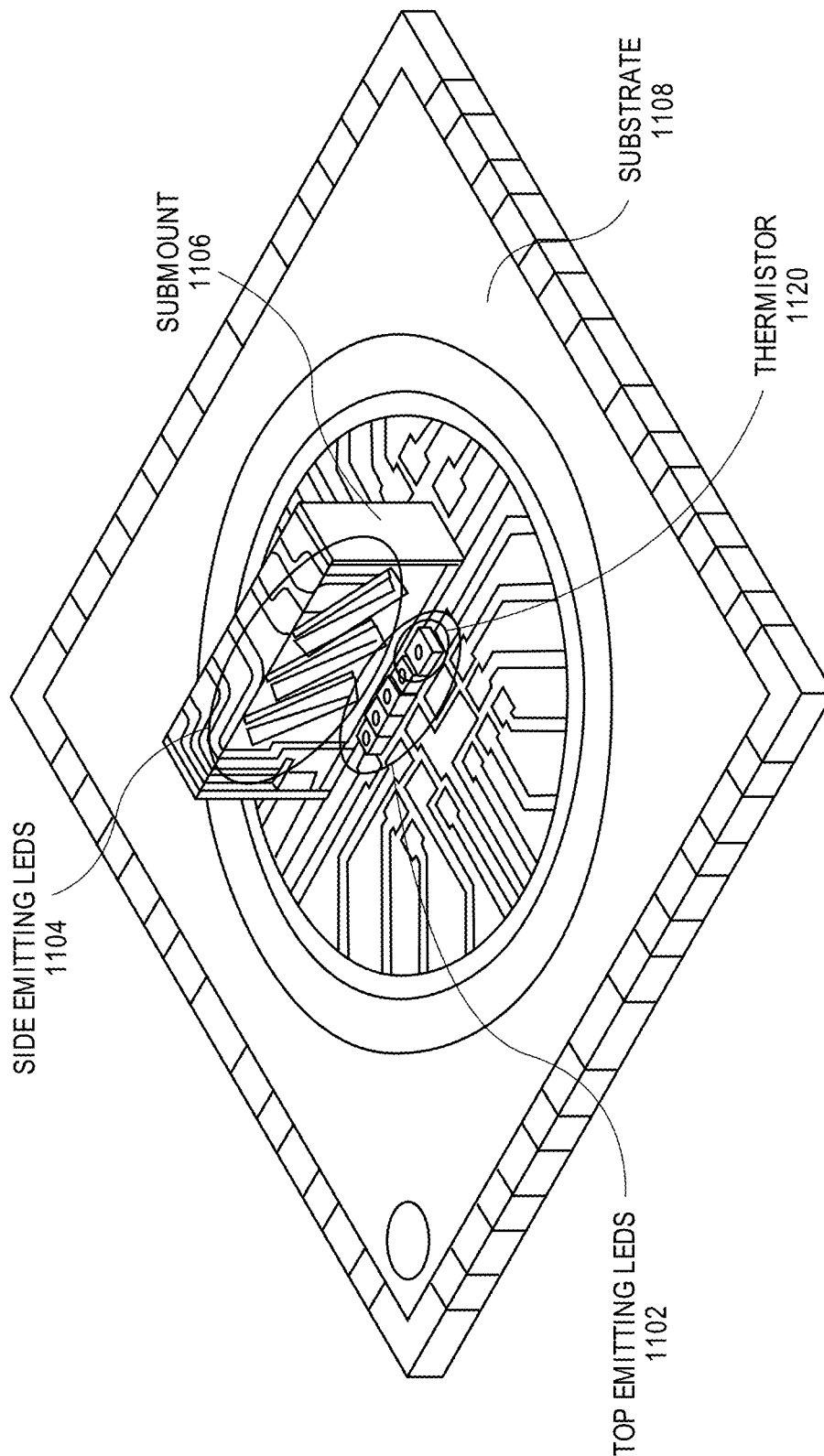


FIG. 11C

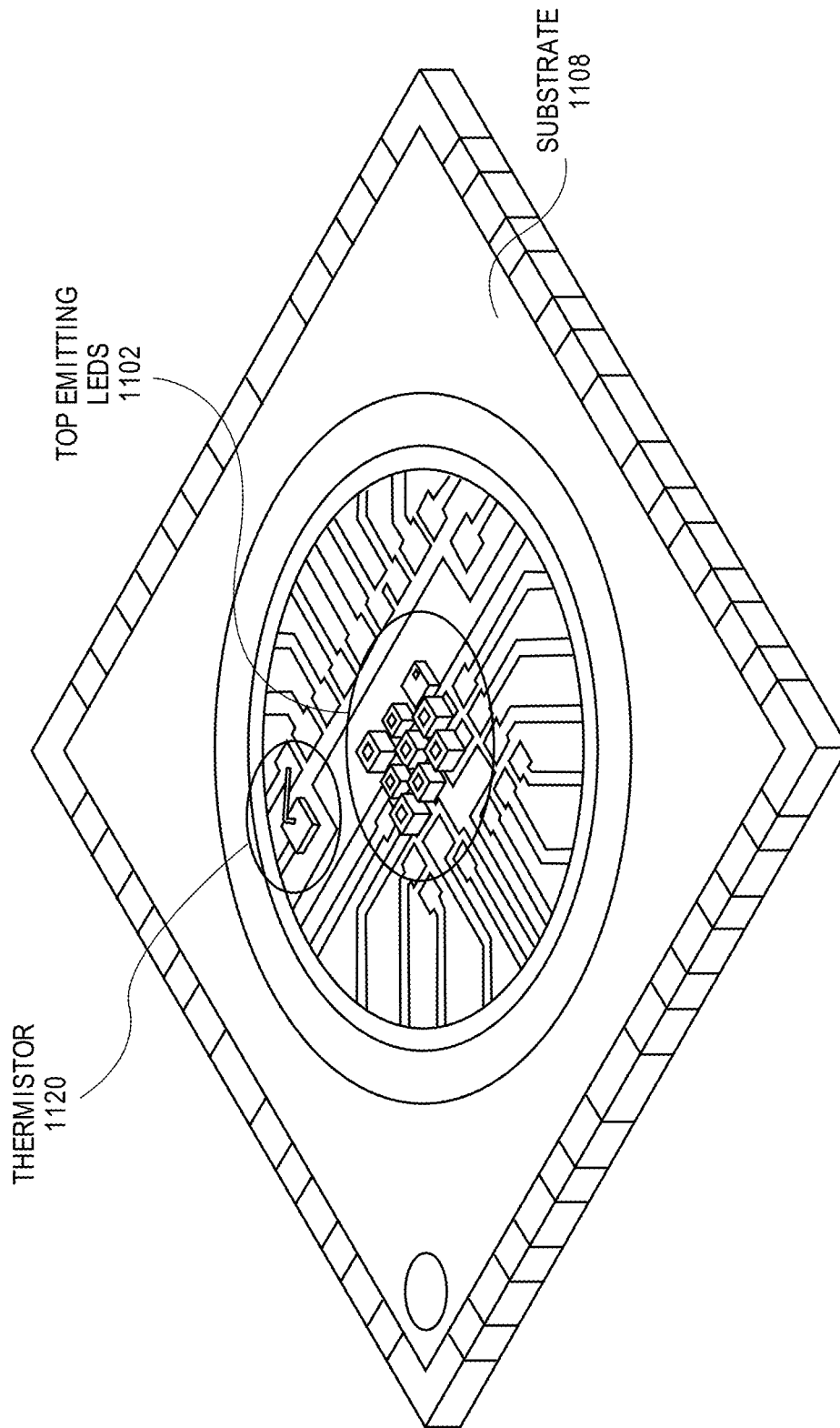


FIG. 11D

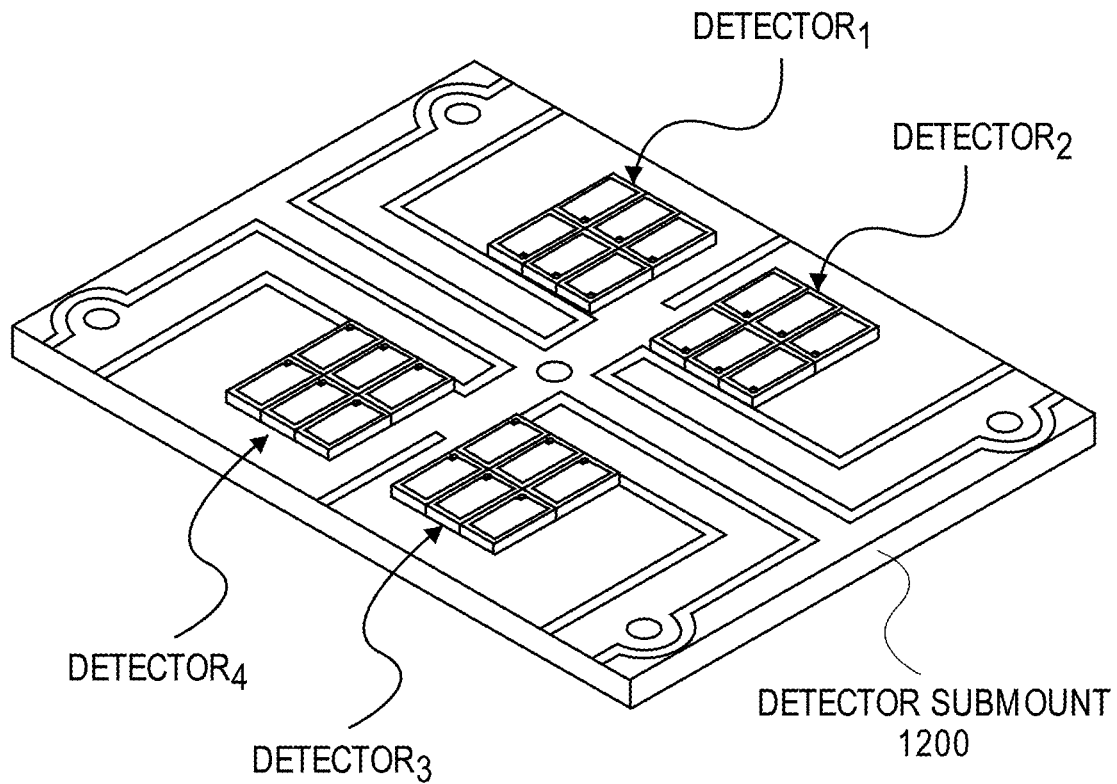


FIG. 12A

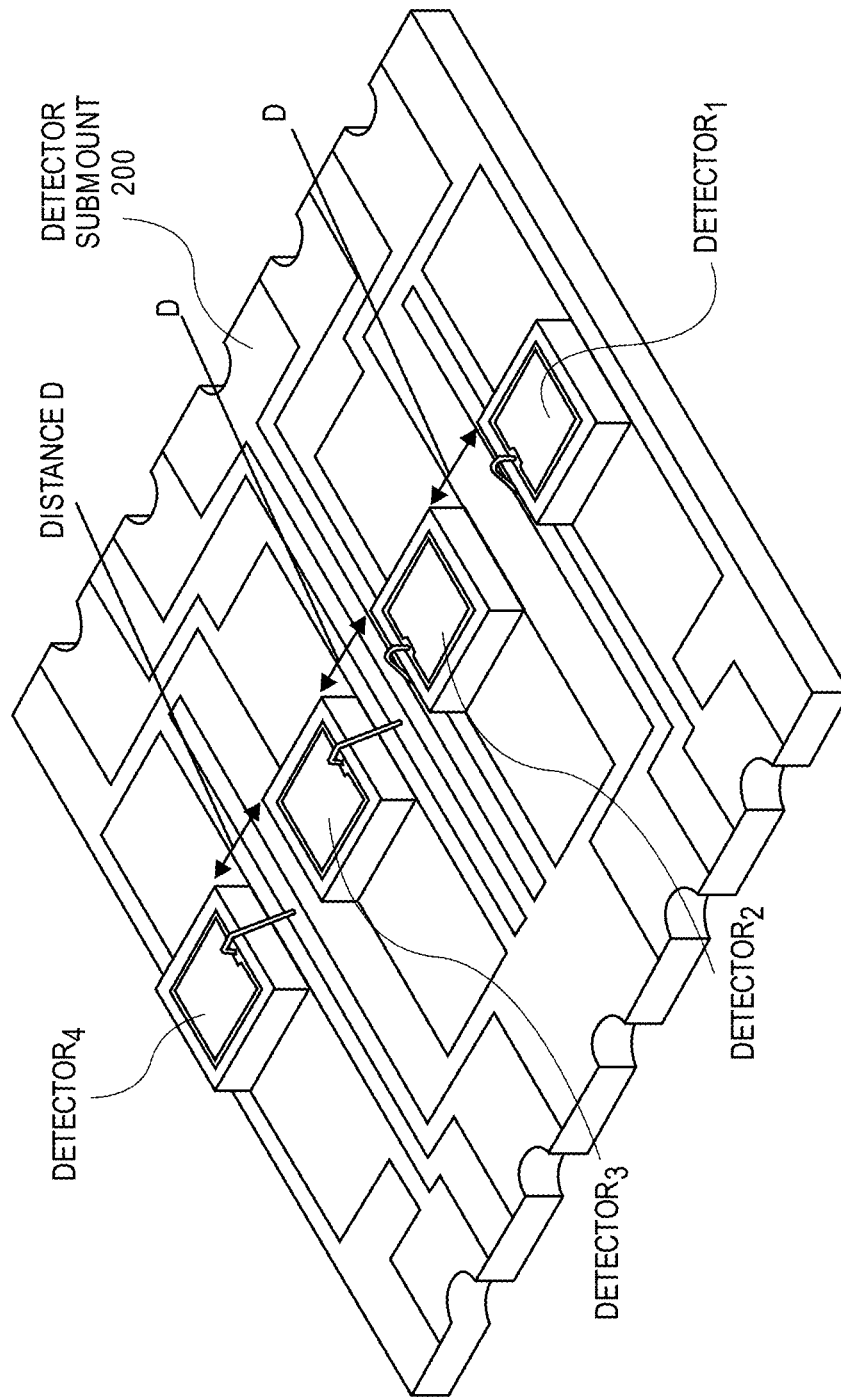


FIG. 12B

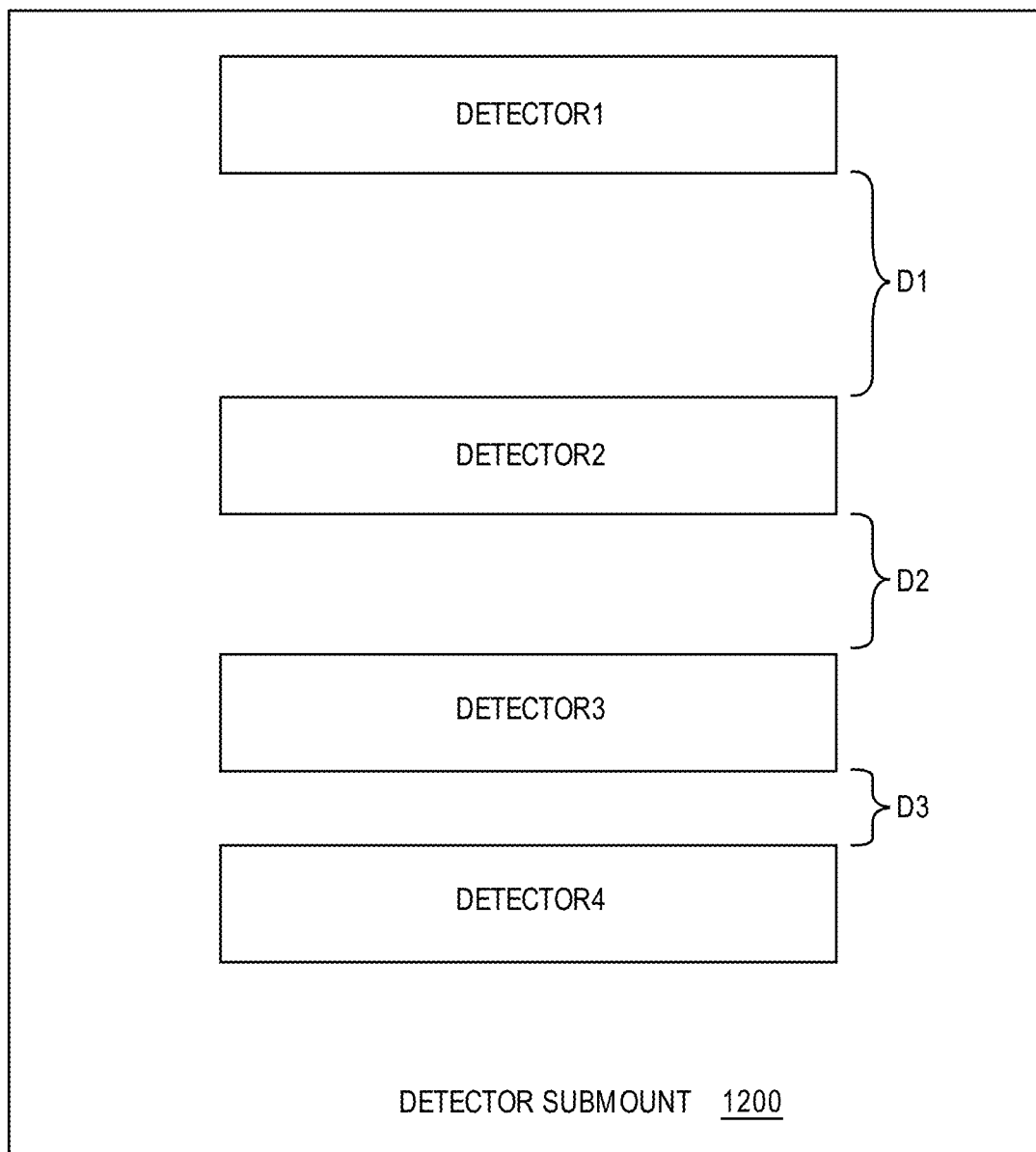


FIG. 12C

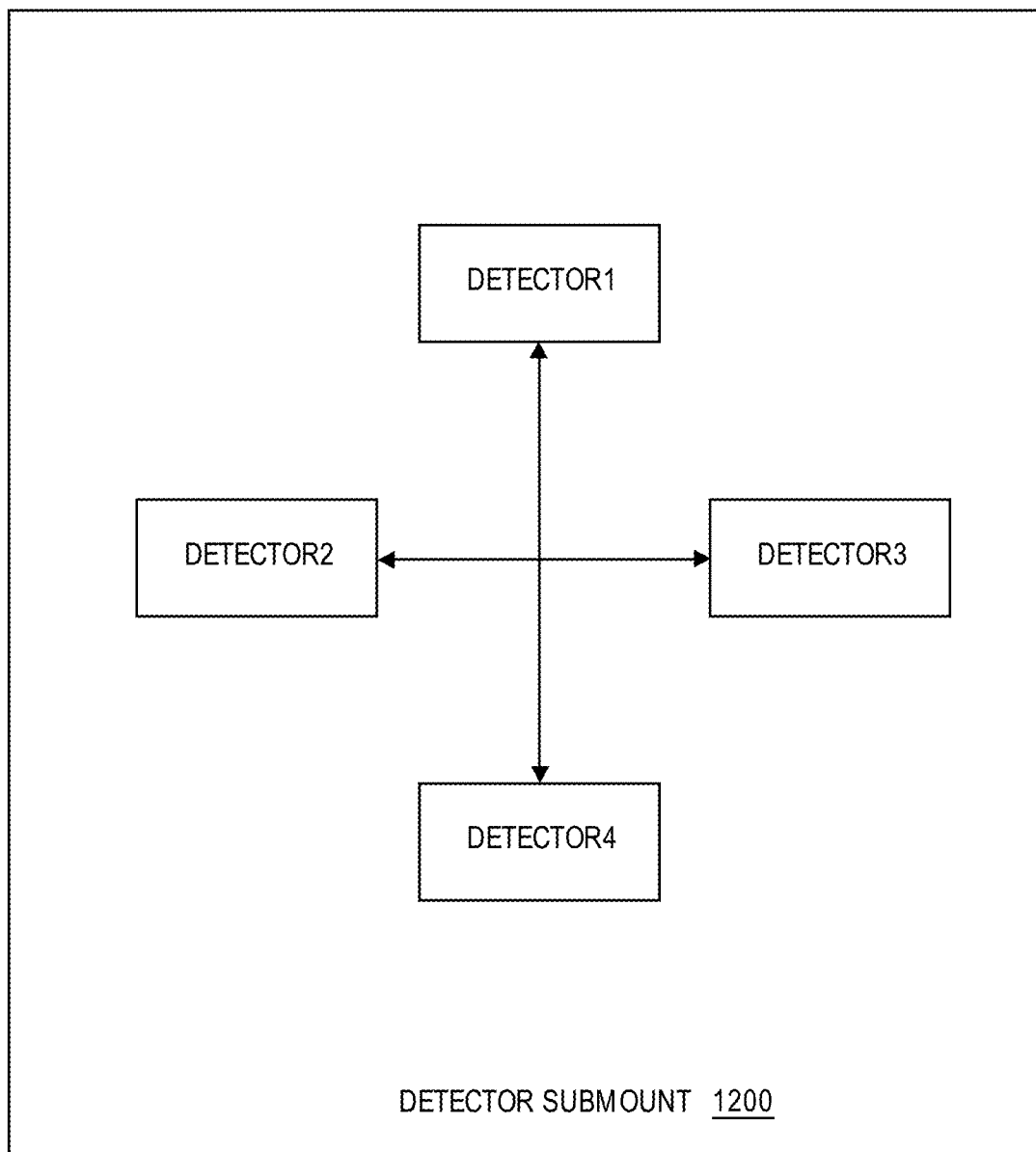


FIG. 12D

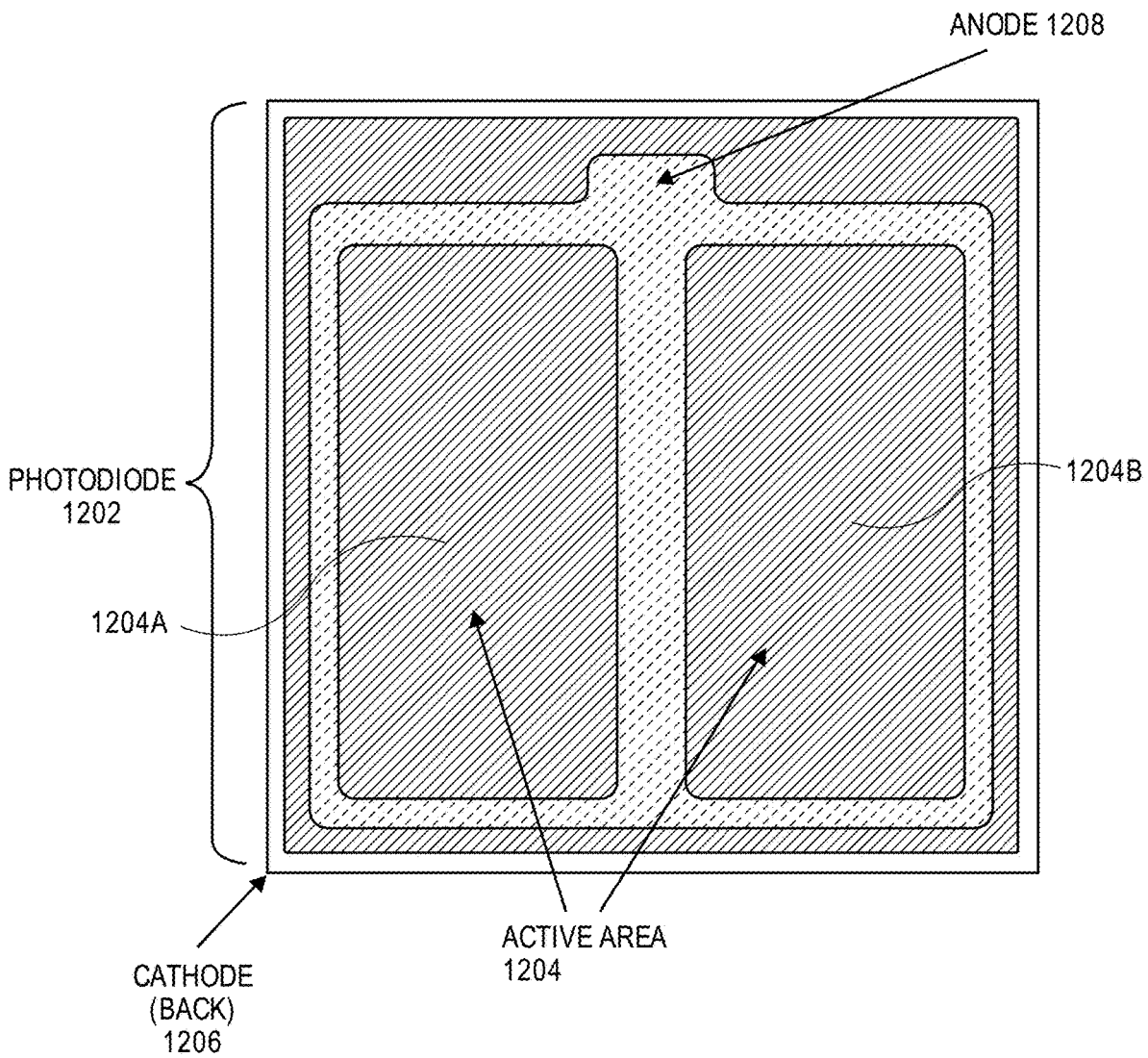


FIG. 12E

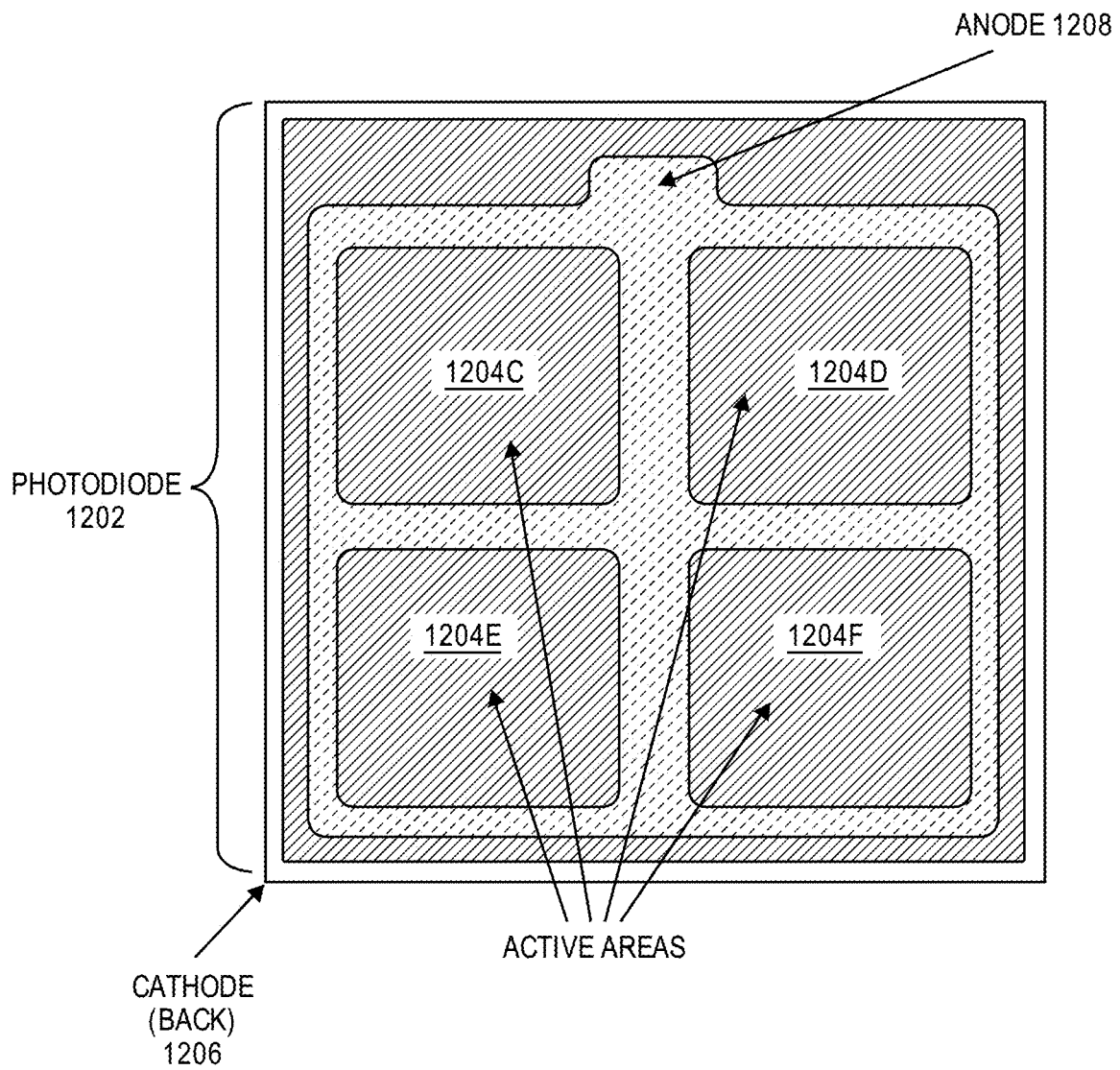


FIG. 12F

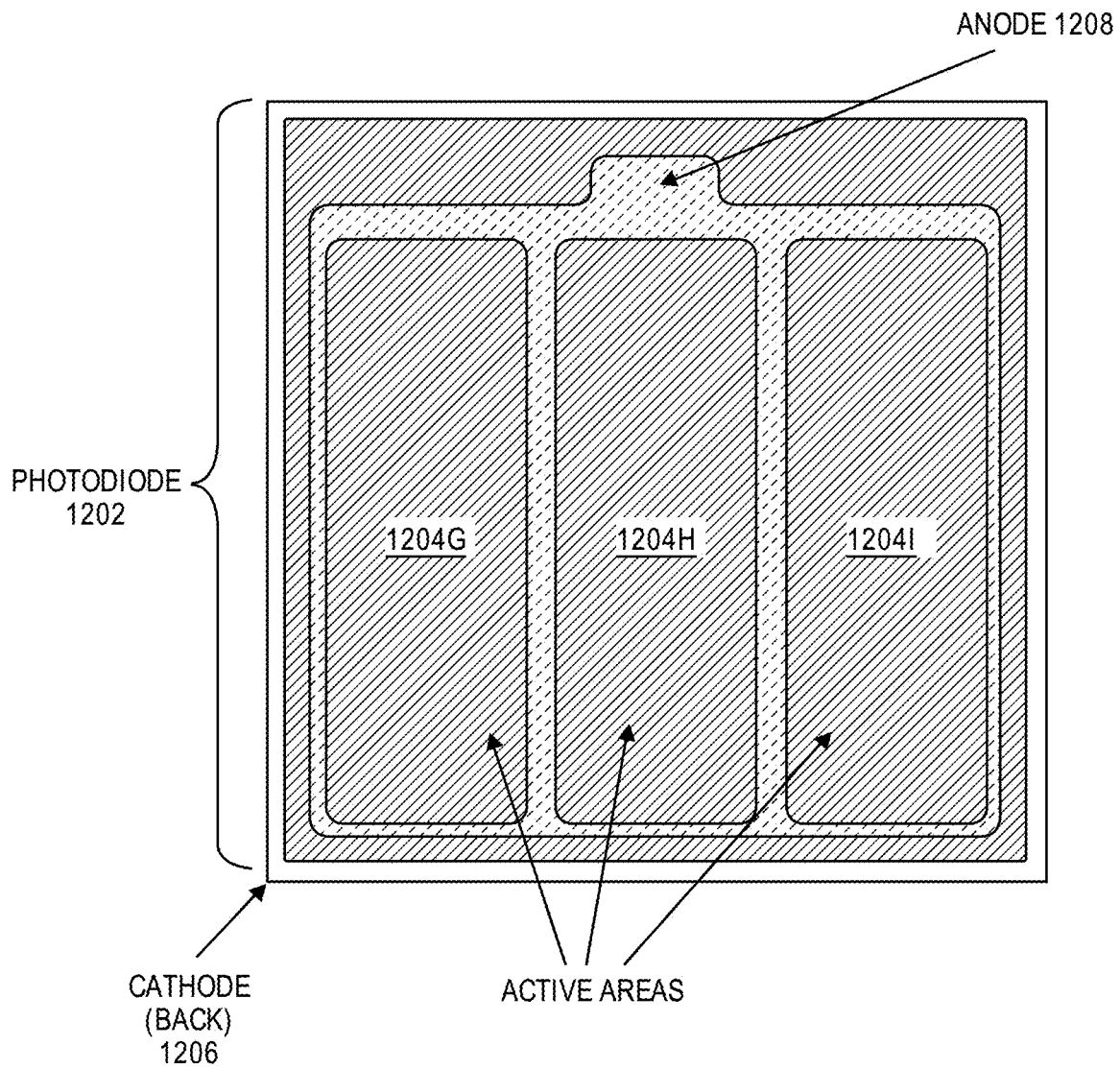


FIG. 12G

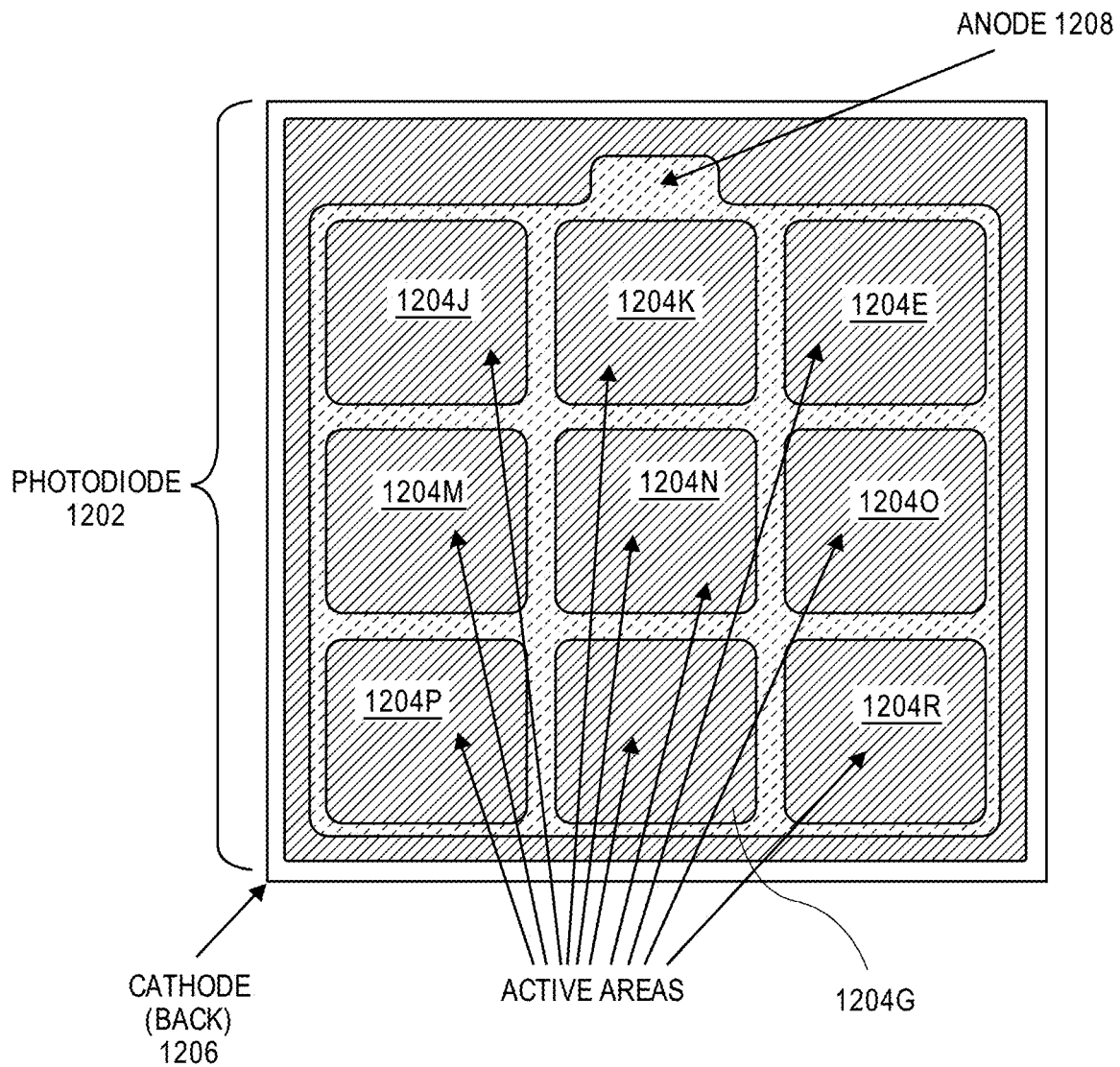
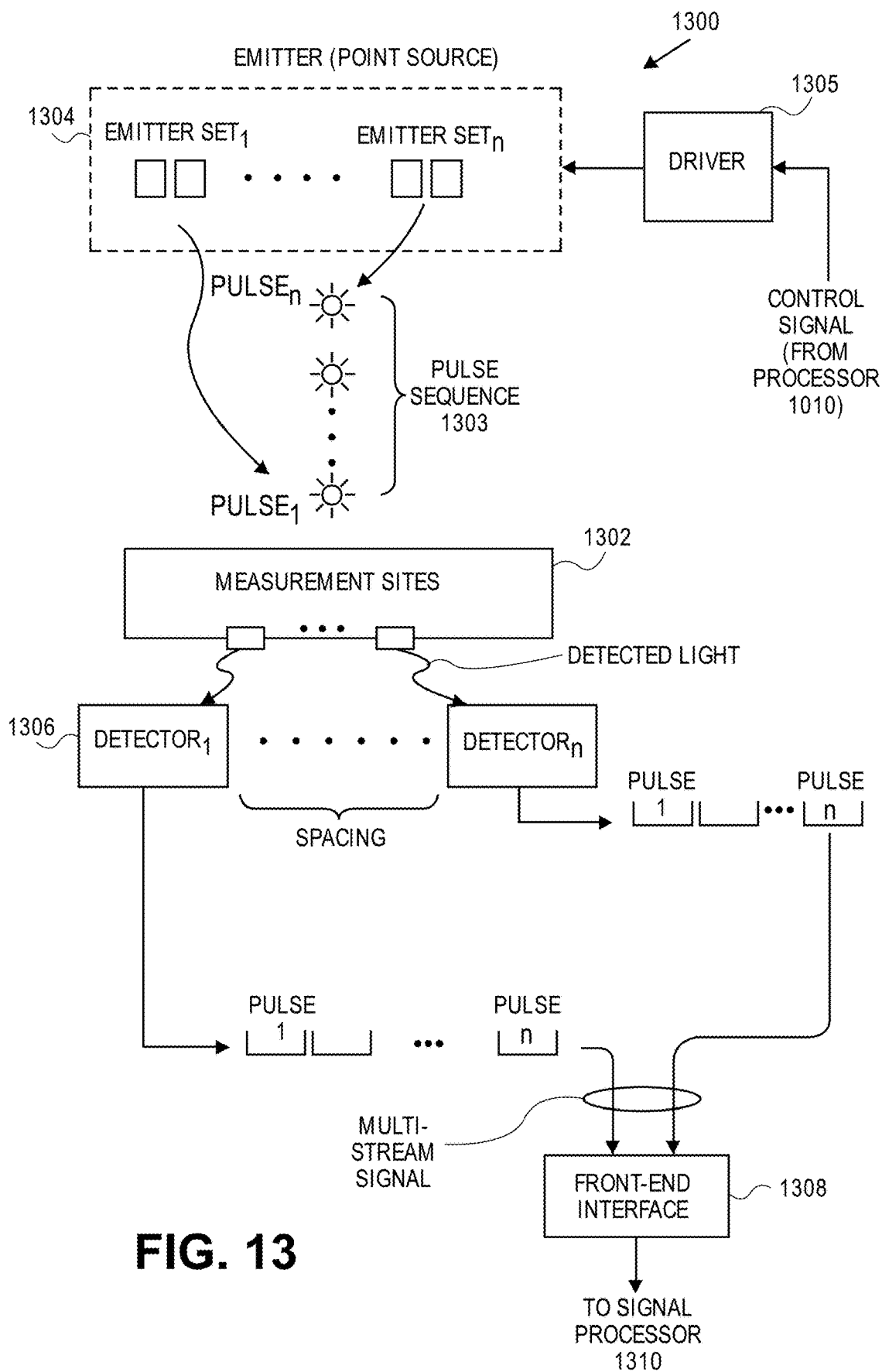


FIG. 12H

**FIG. 13**

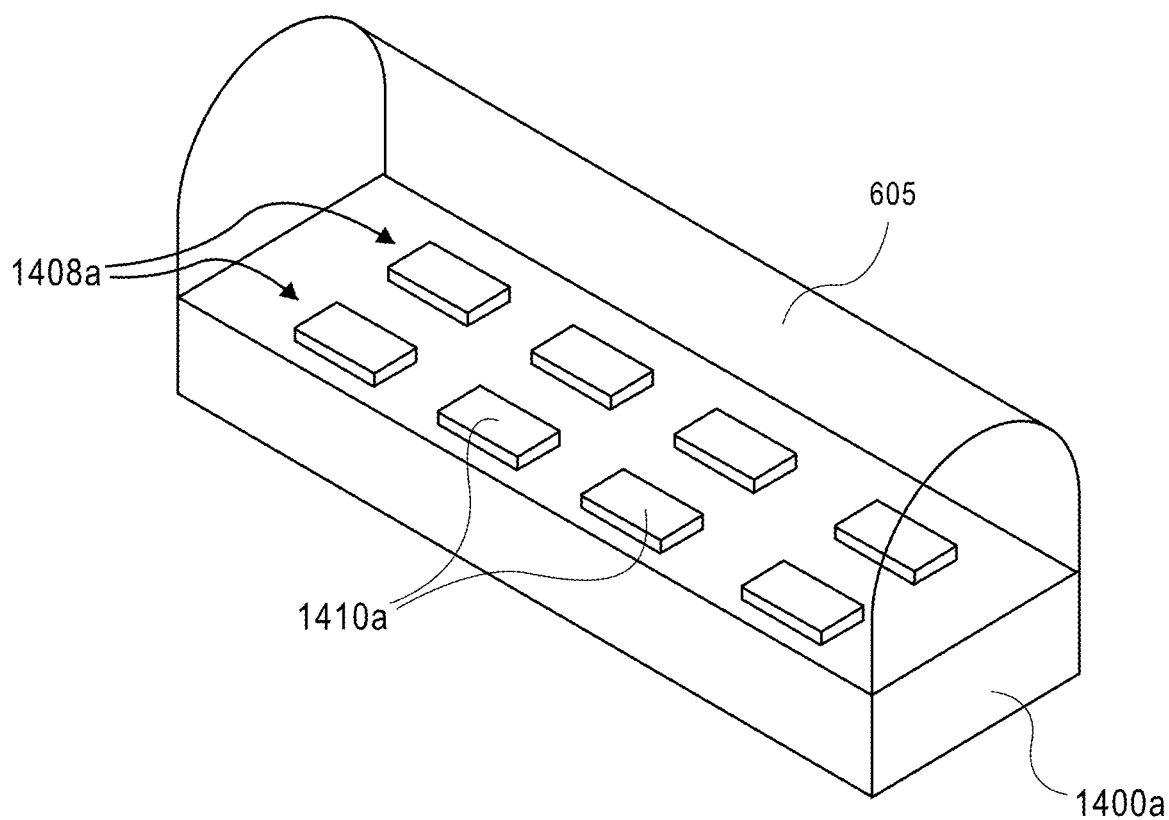


FIG. 14A

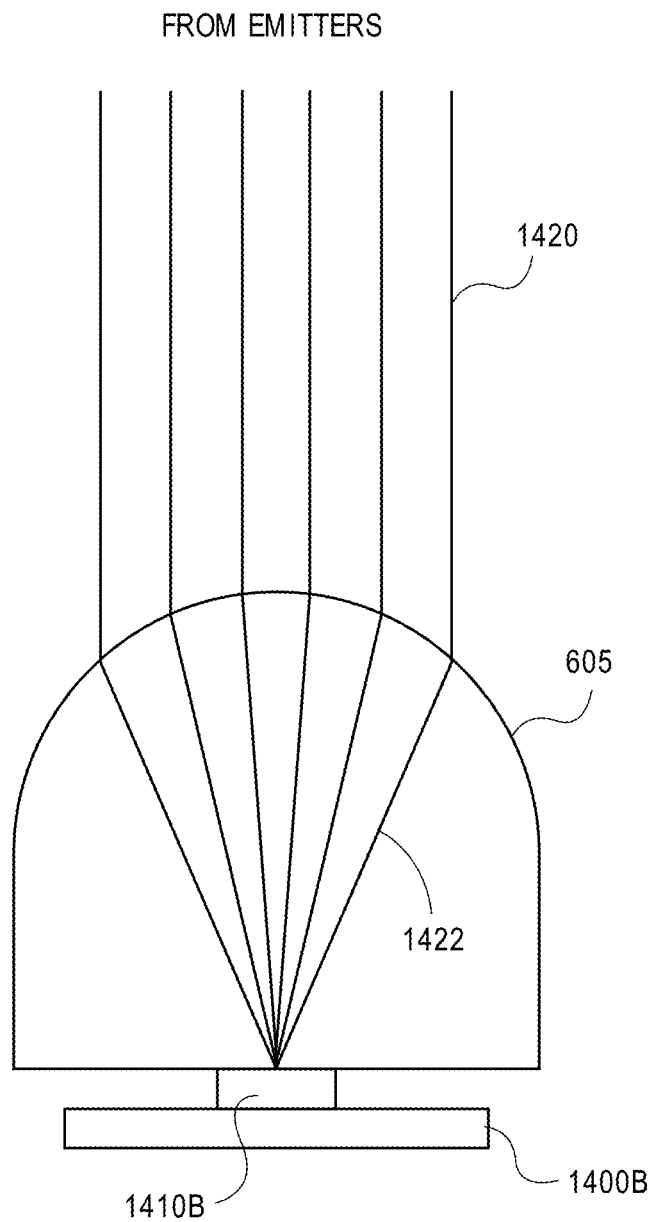


FIG. 14B

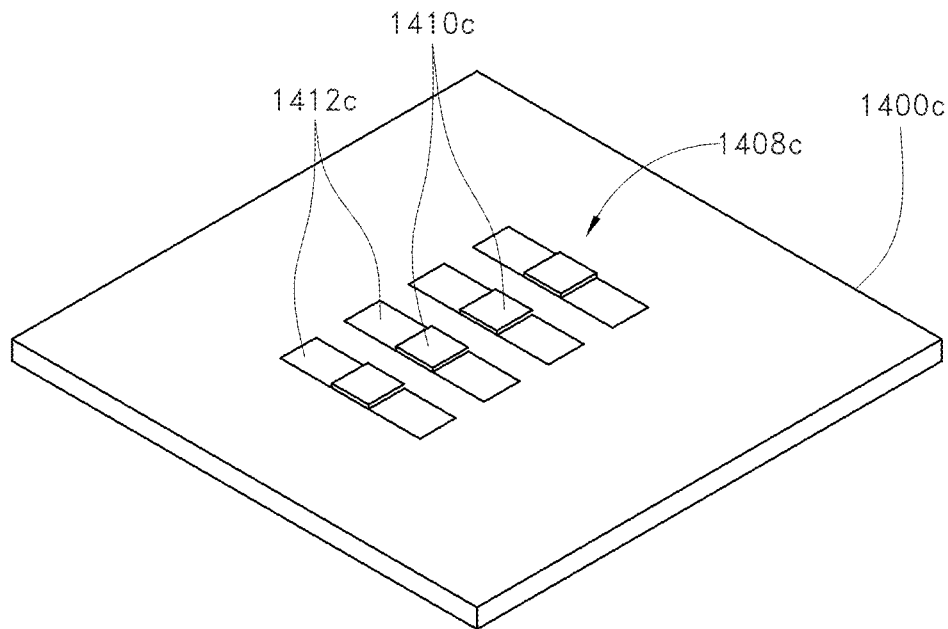


FIG. 14C

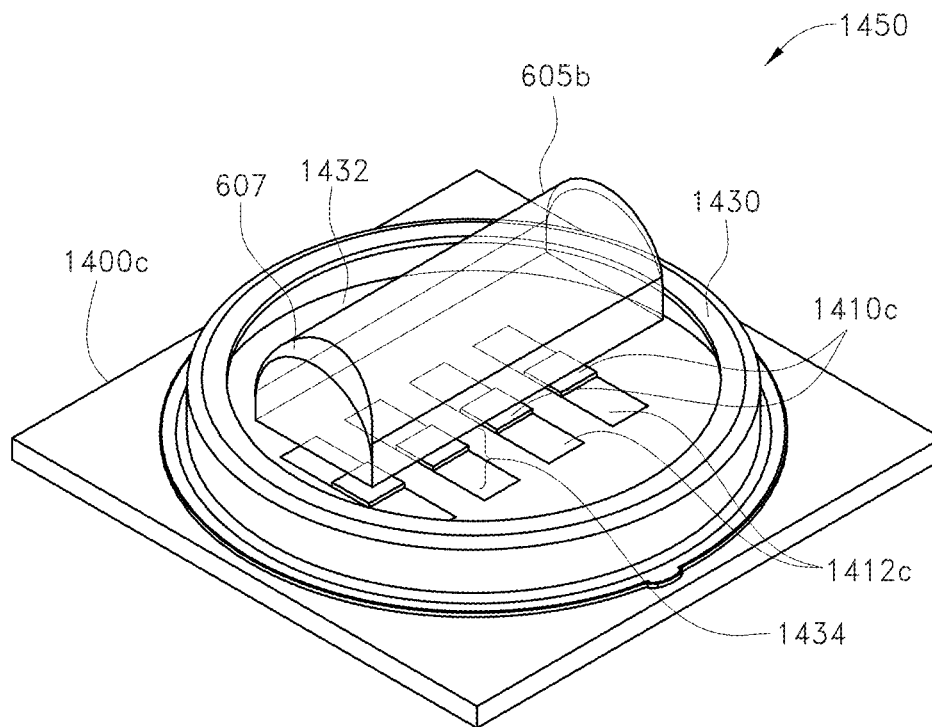


FIG. 14D

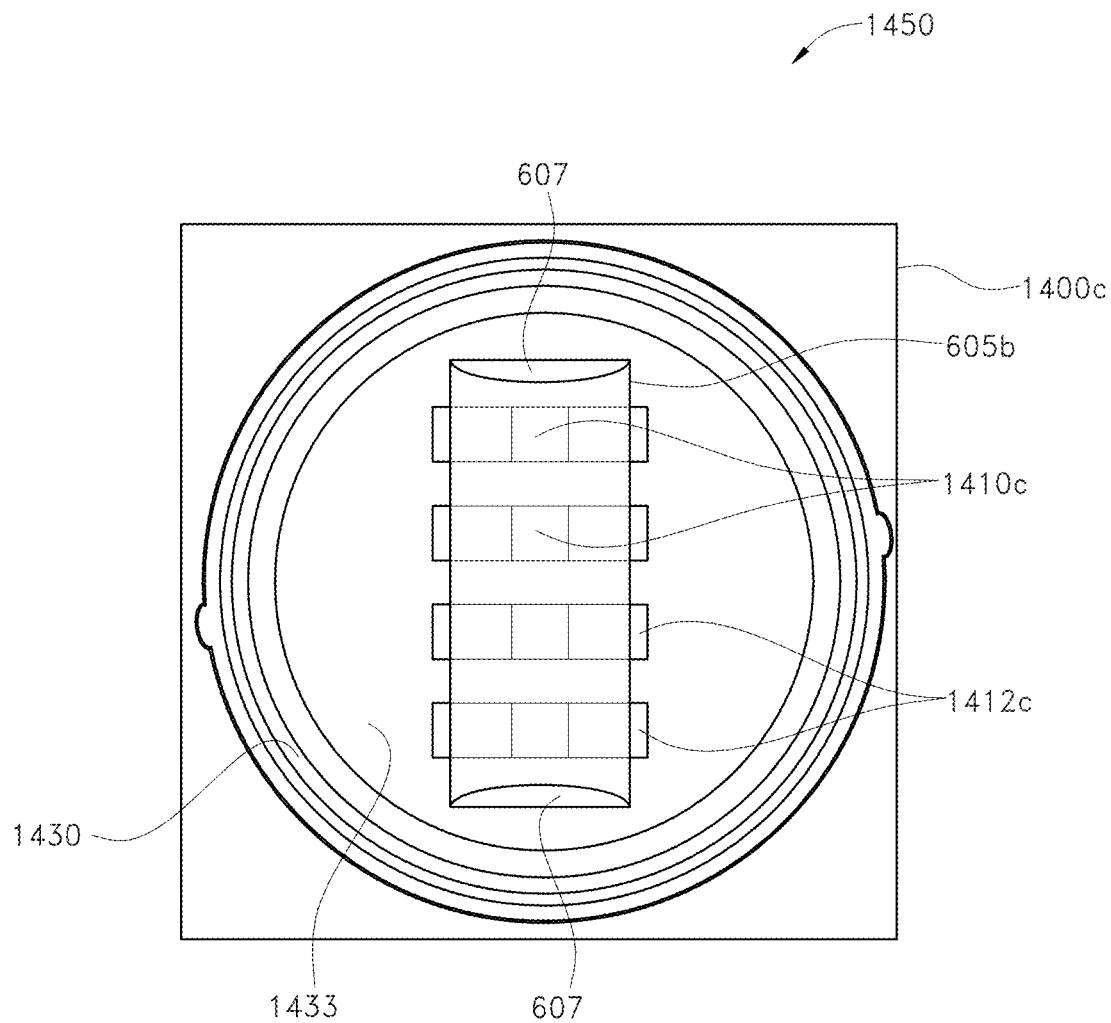


FIG. 14E

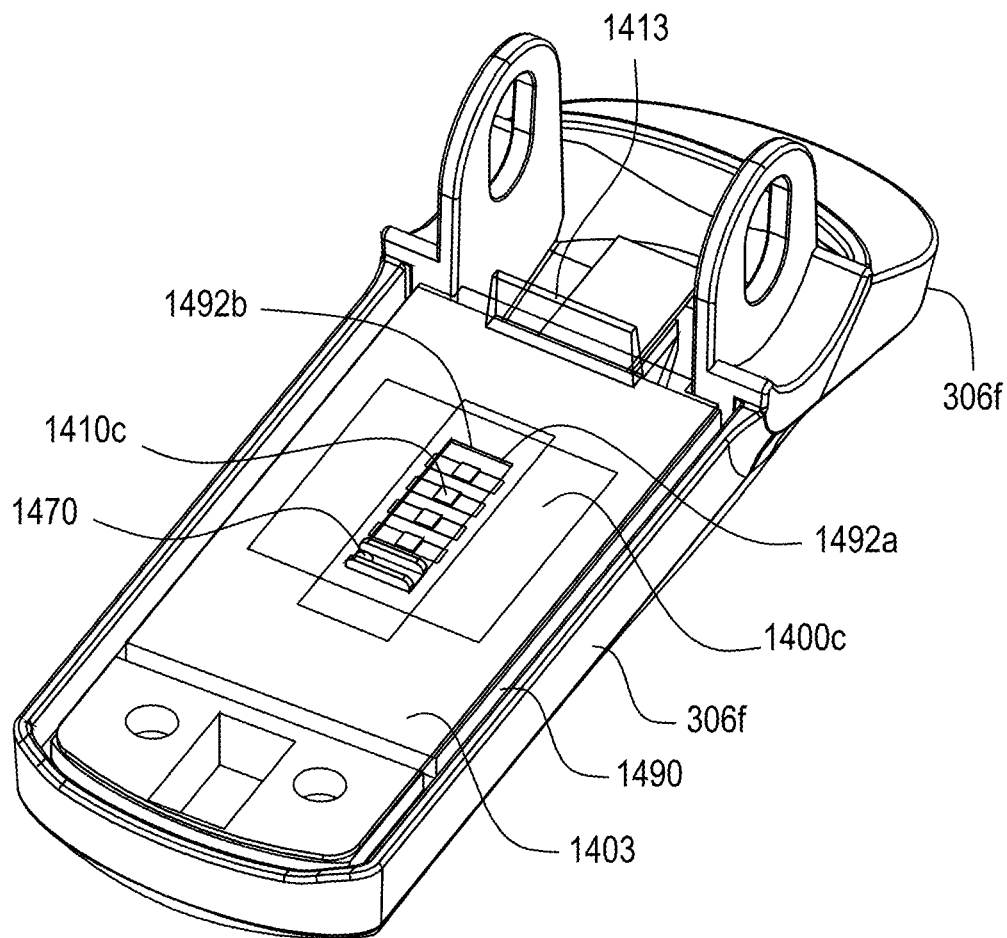


FIG. 14F

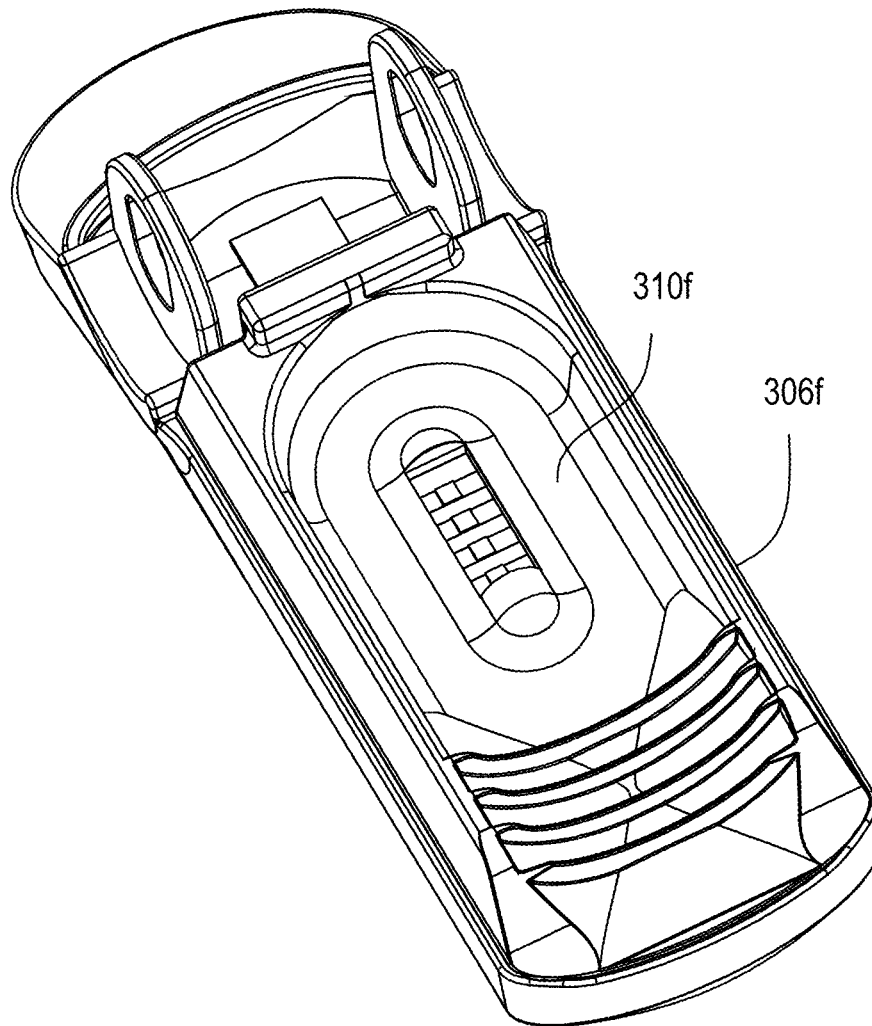


FIG. 14G

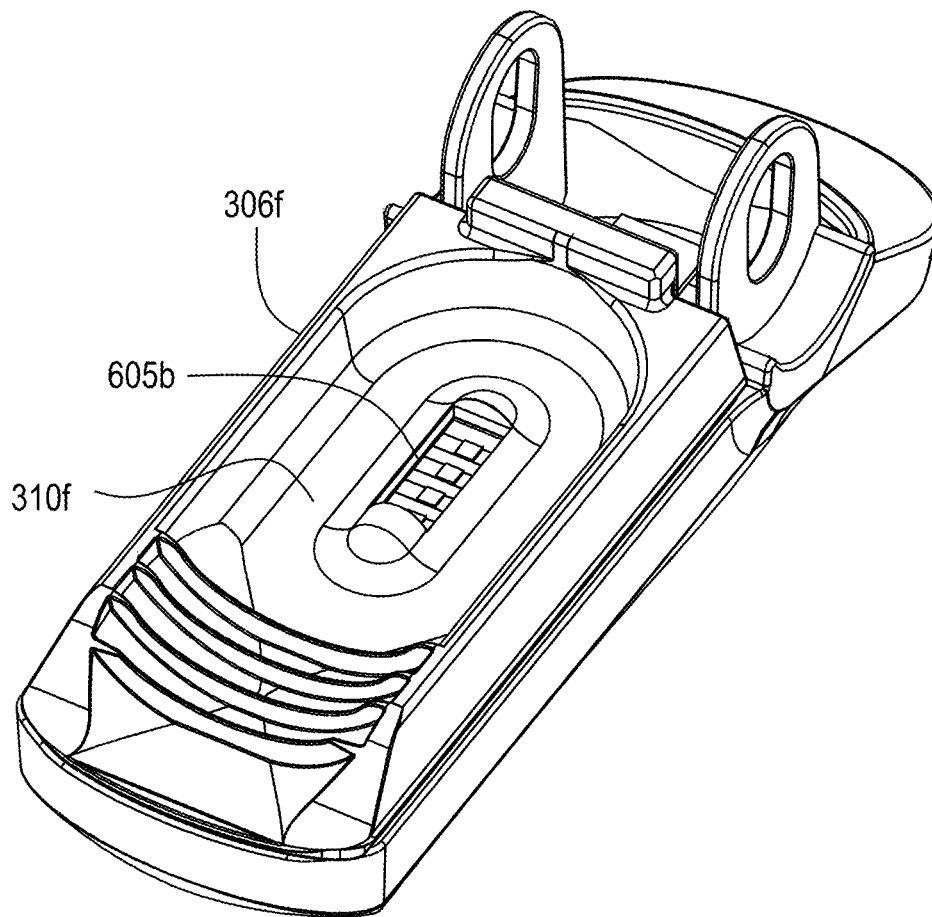


FIG. 14H

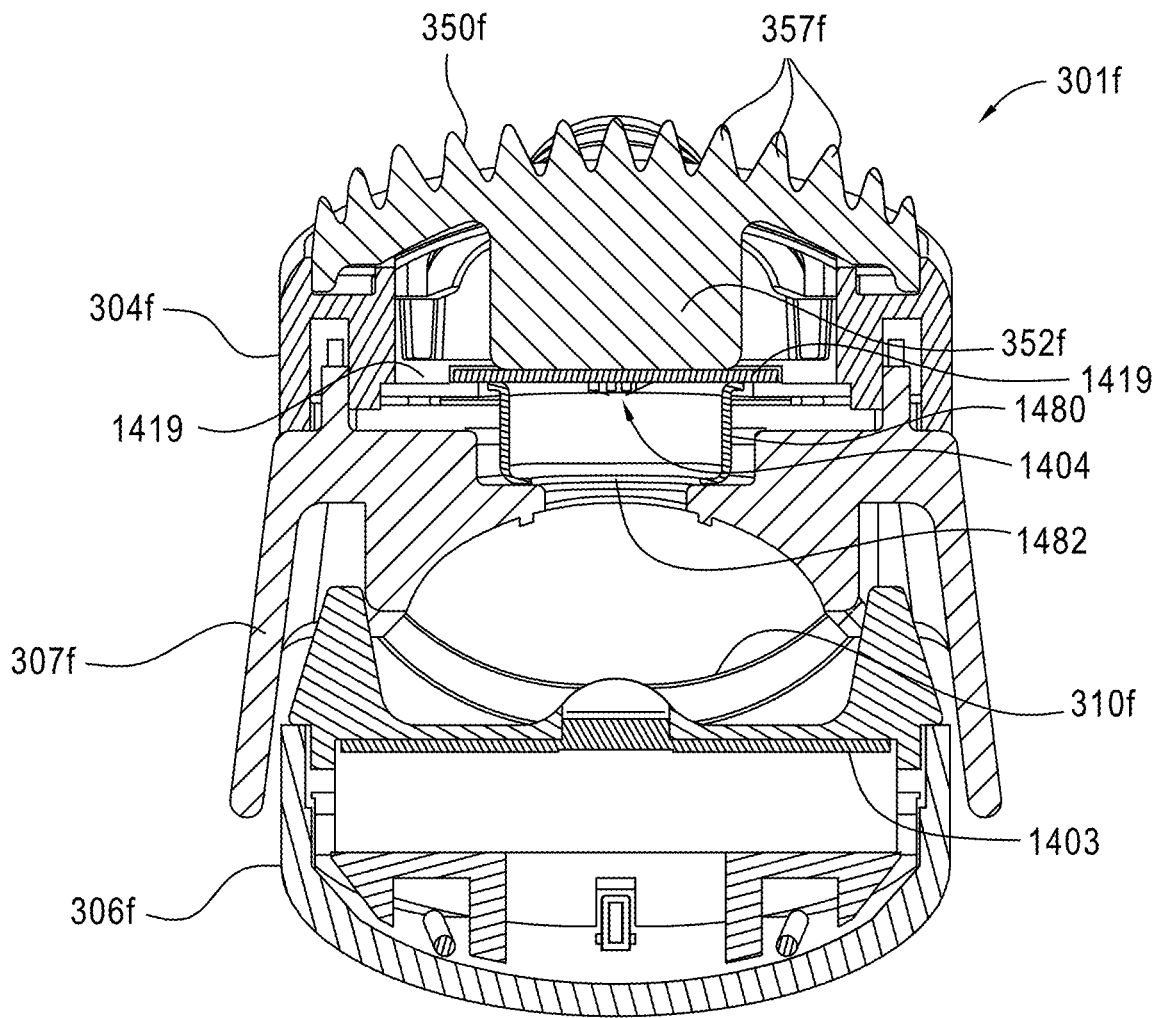


FIG. 14I

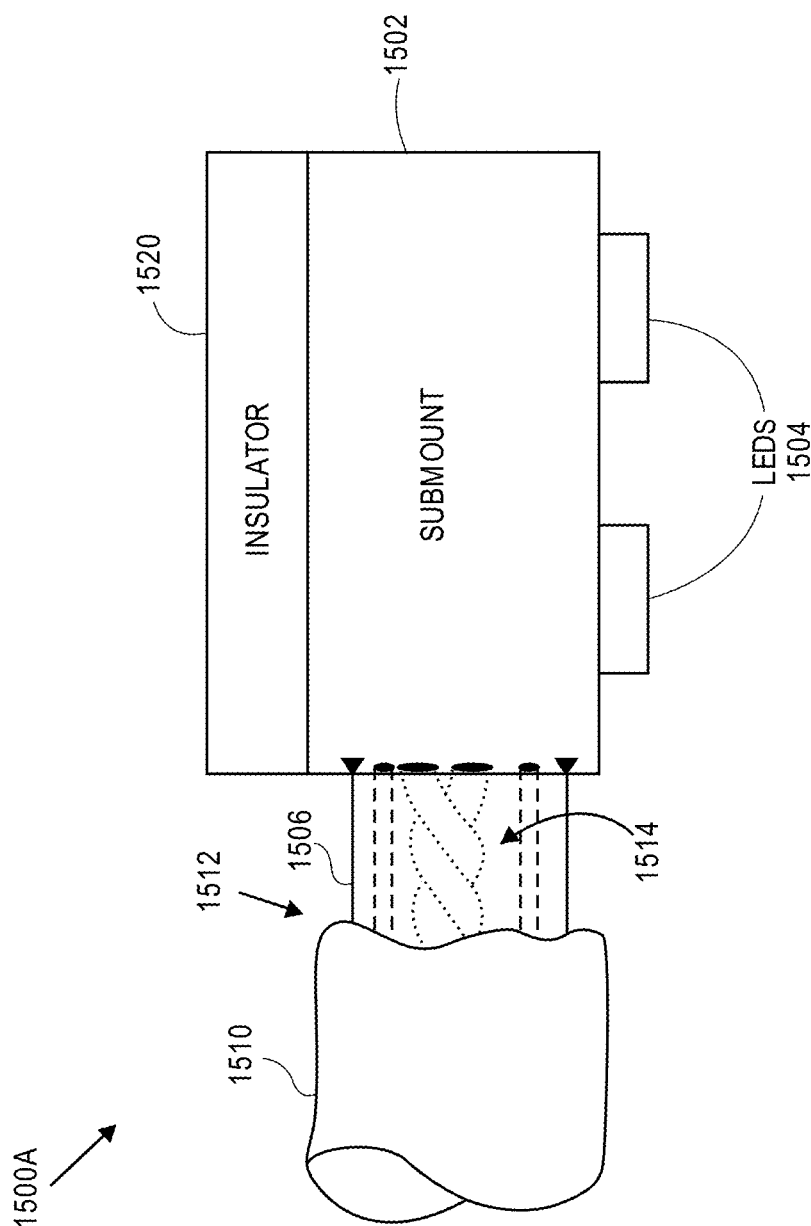


FIG. 15A

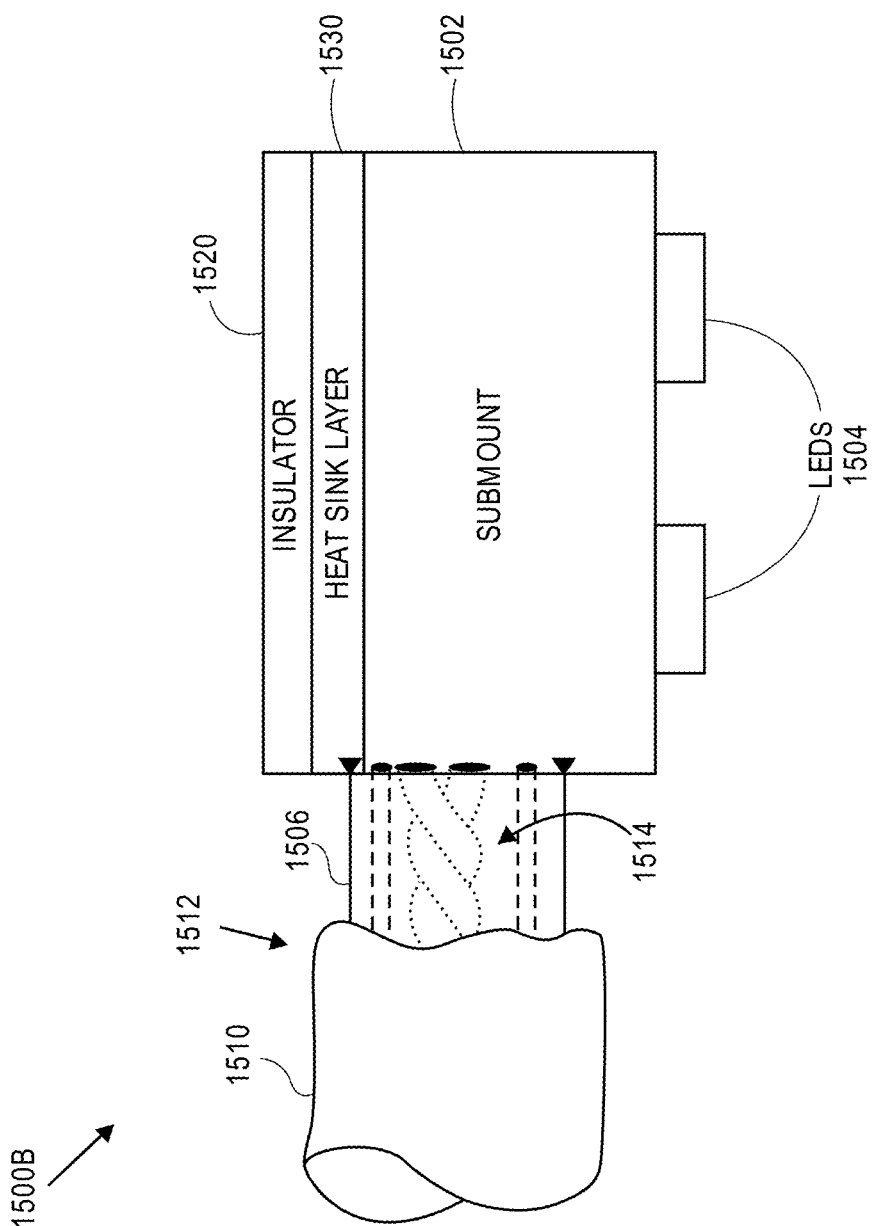


FIG. 15B

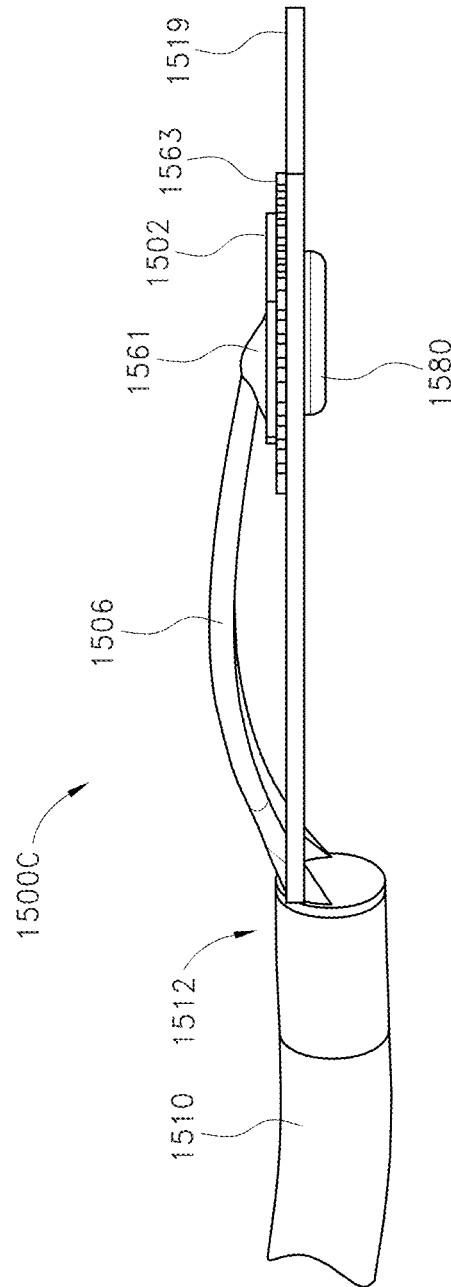


FIG. 15C

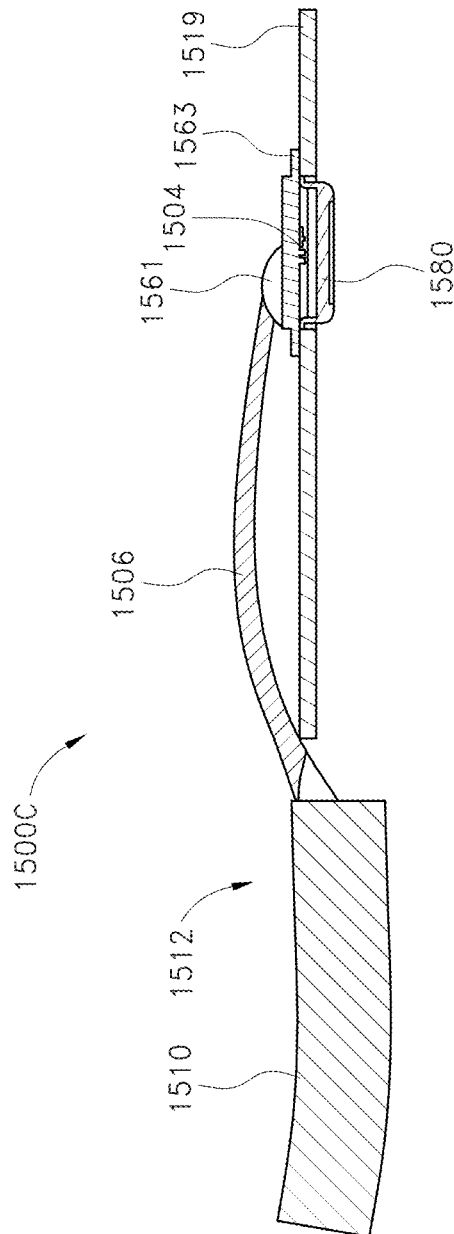


FIG. 15D

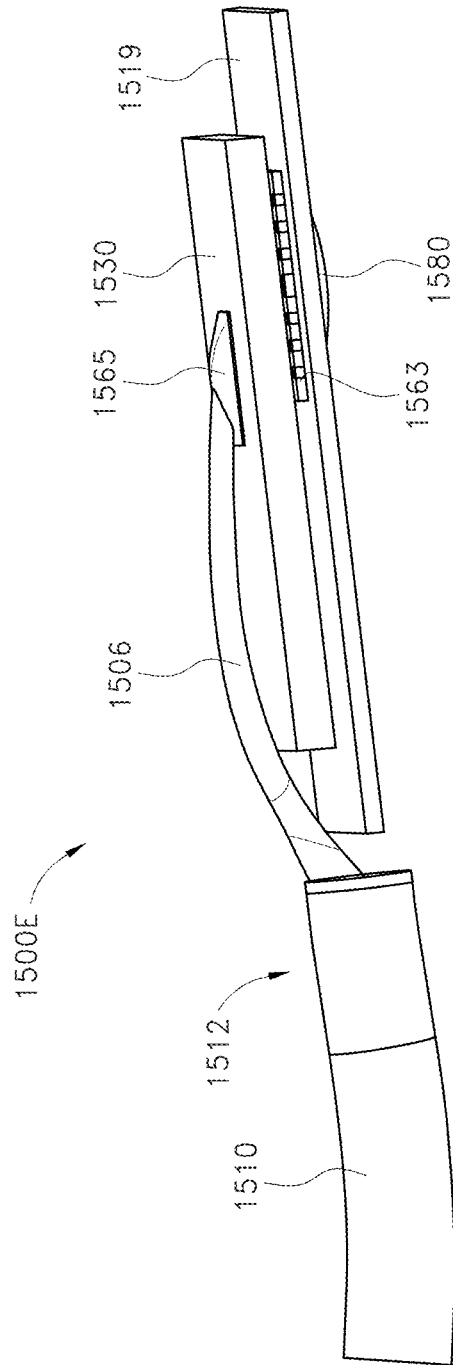


FIG. 15E

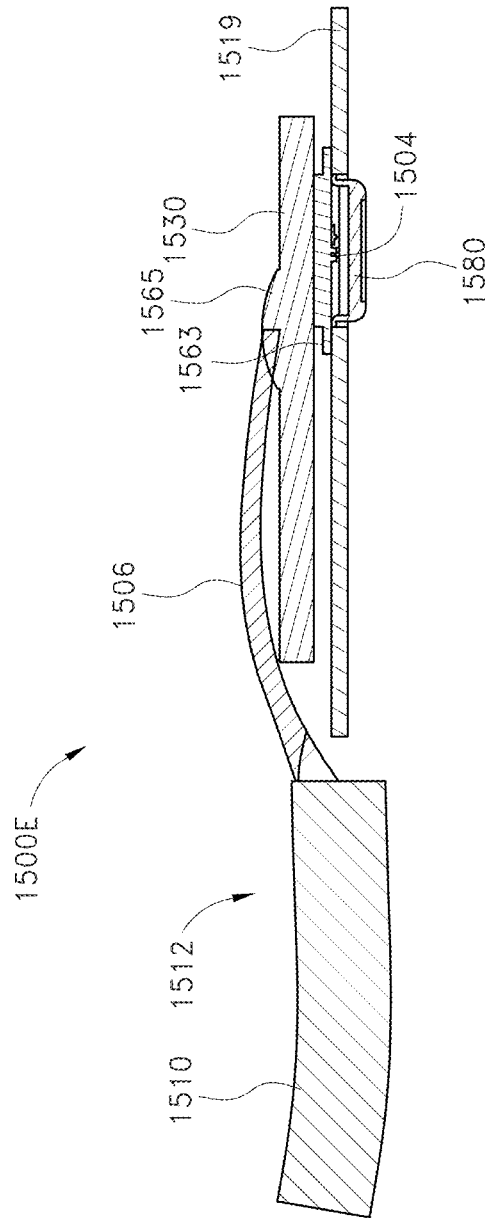


FIG. 15F

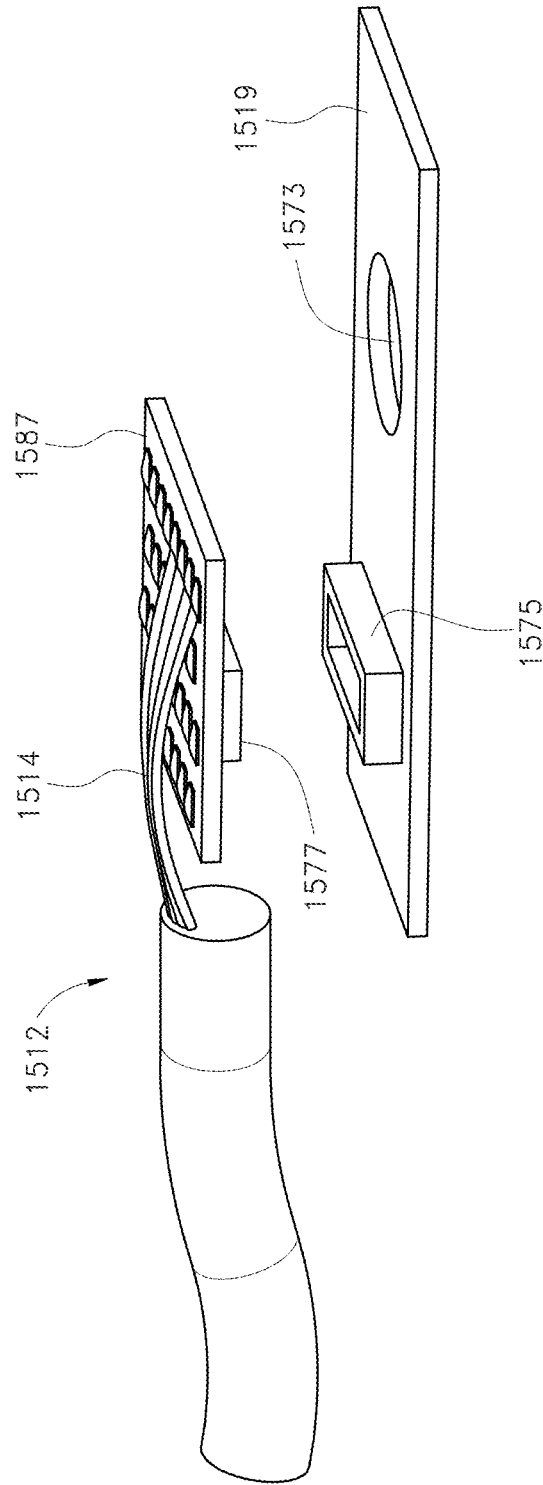


FIG. 15G

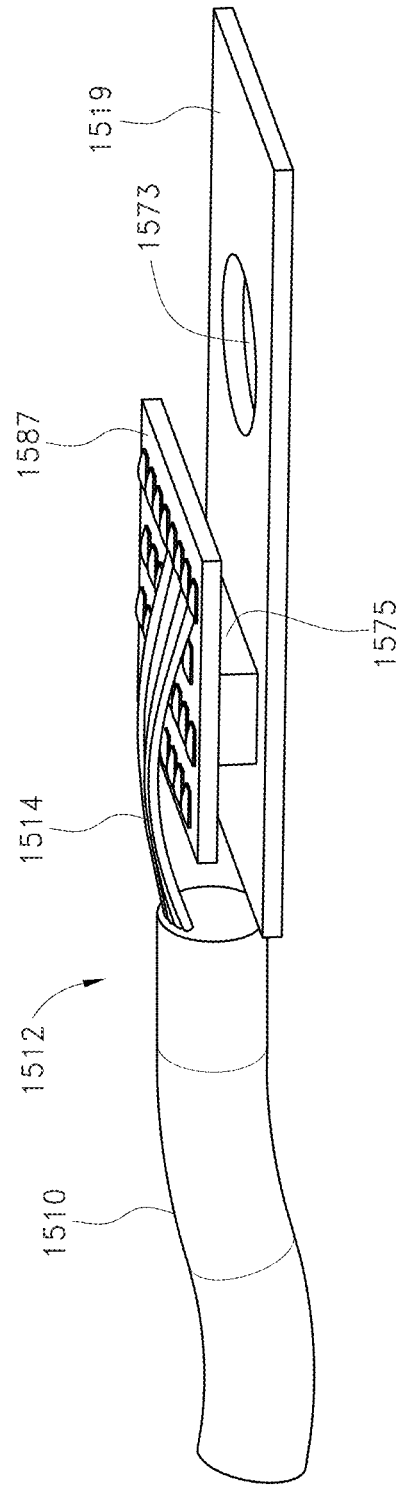


FIG. 15H

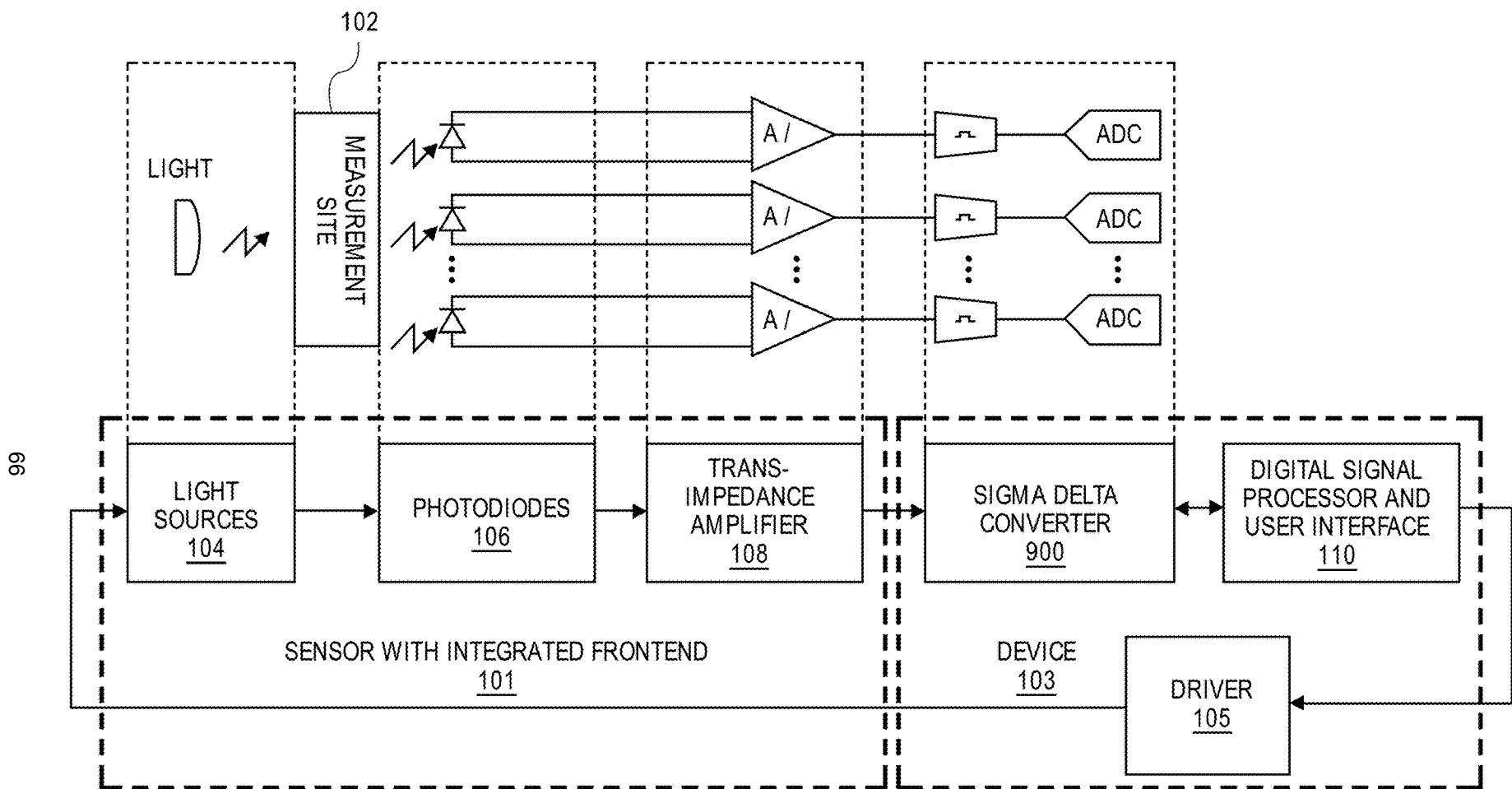


FIG. 15I

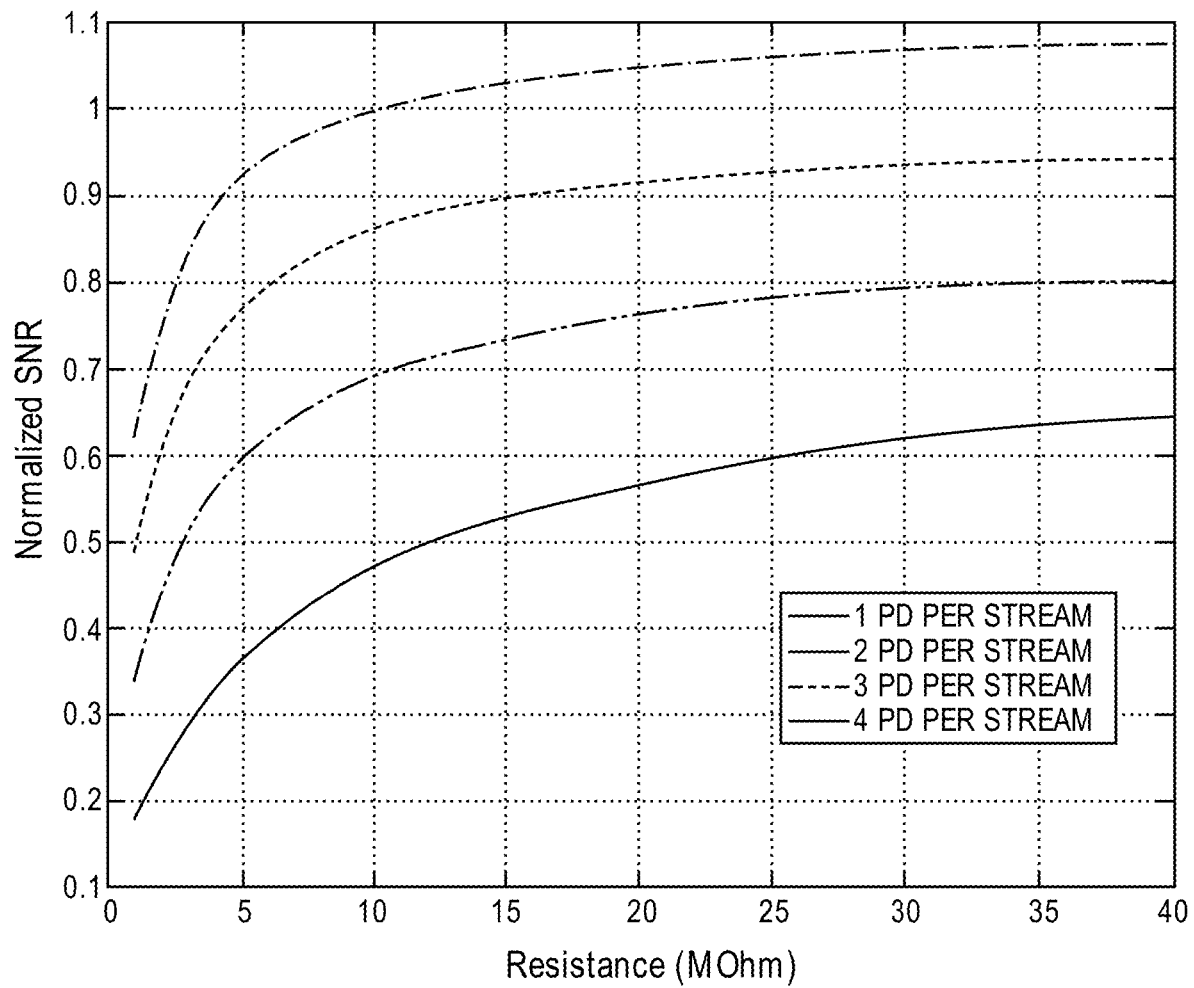
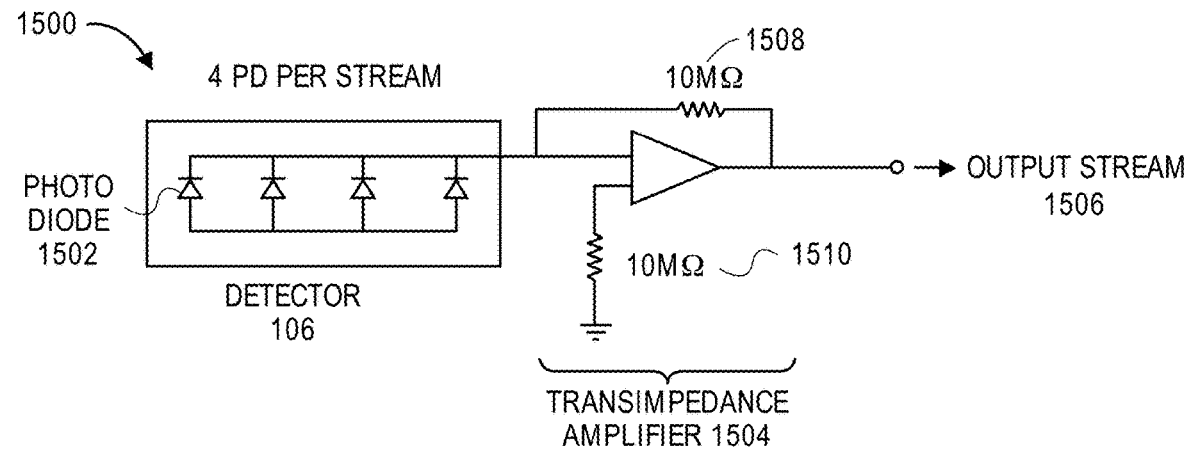


FIG. 15J



VS.

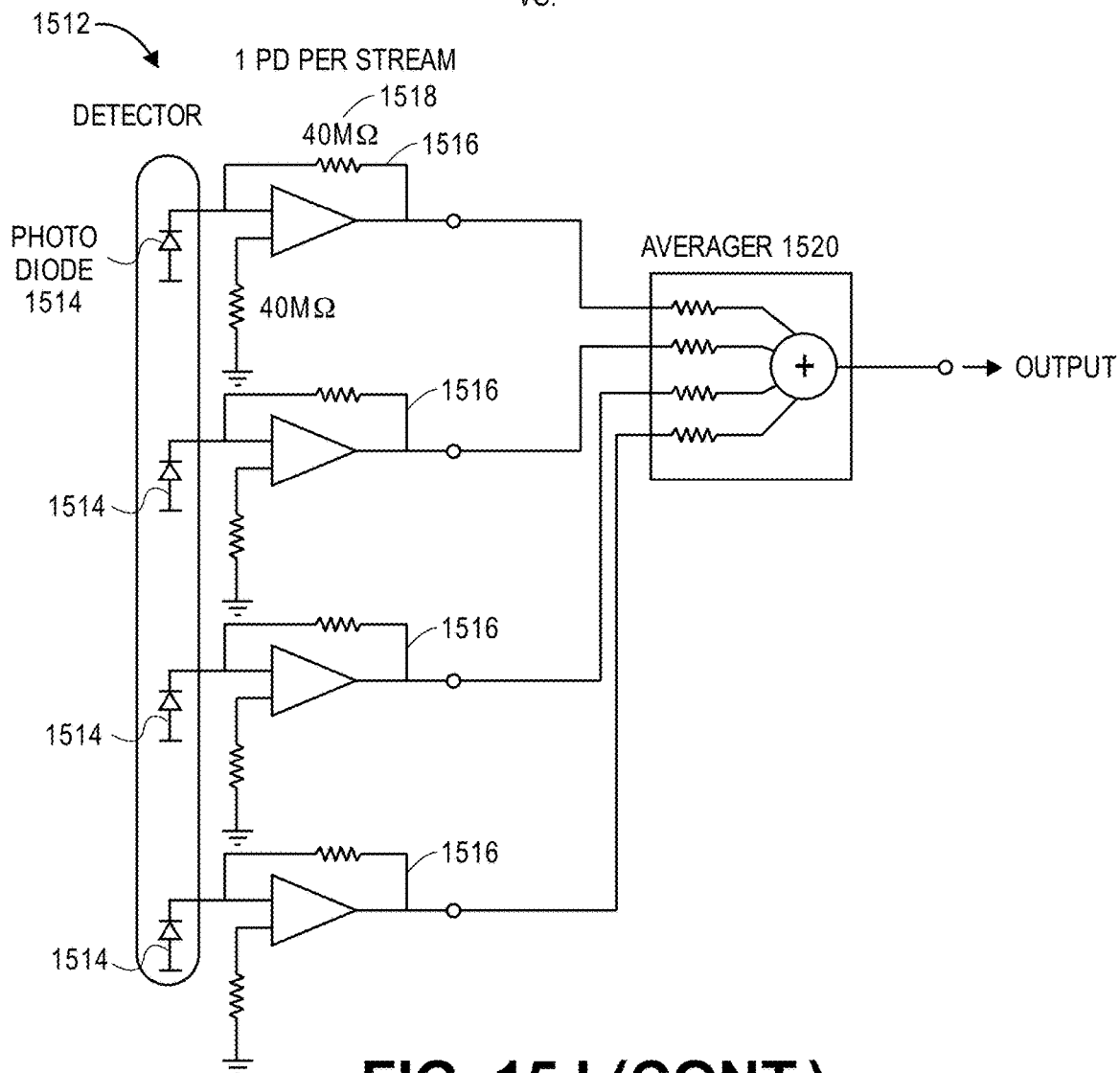


FIG. 15J (CONT.)

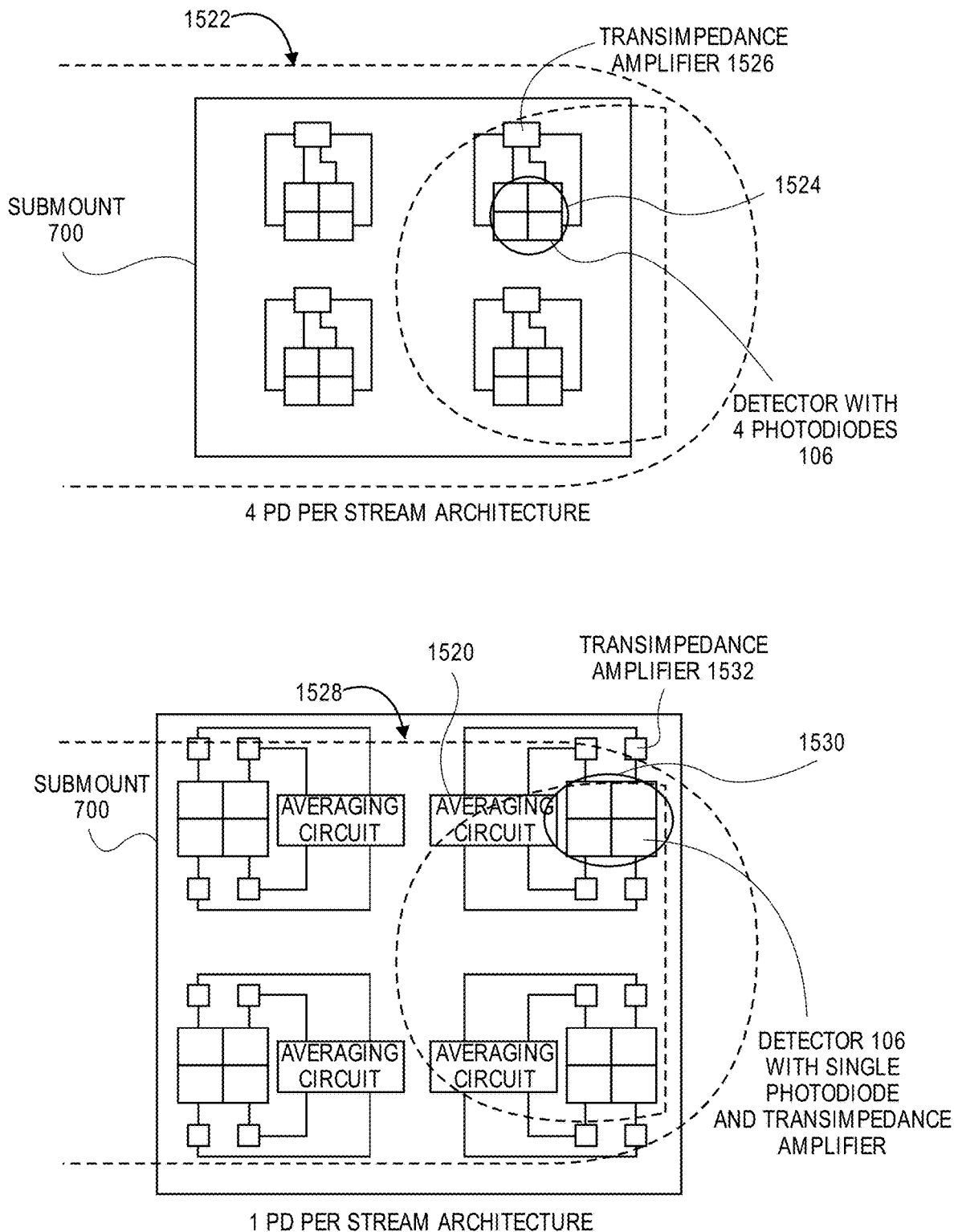


FIG. 15K

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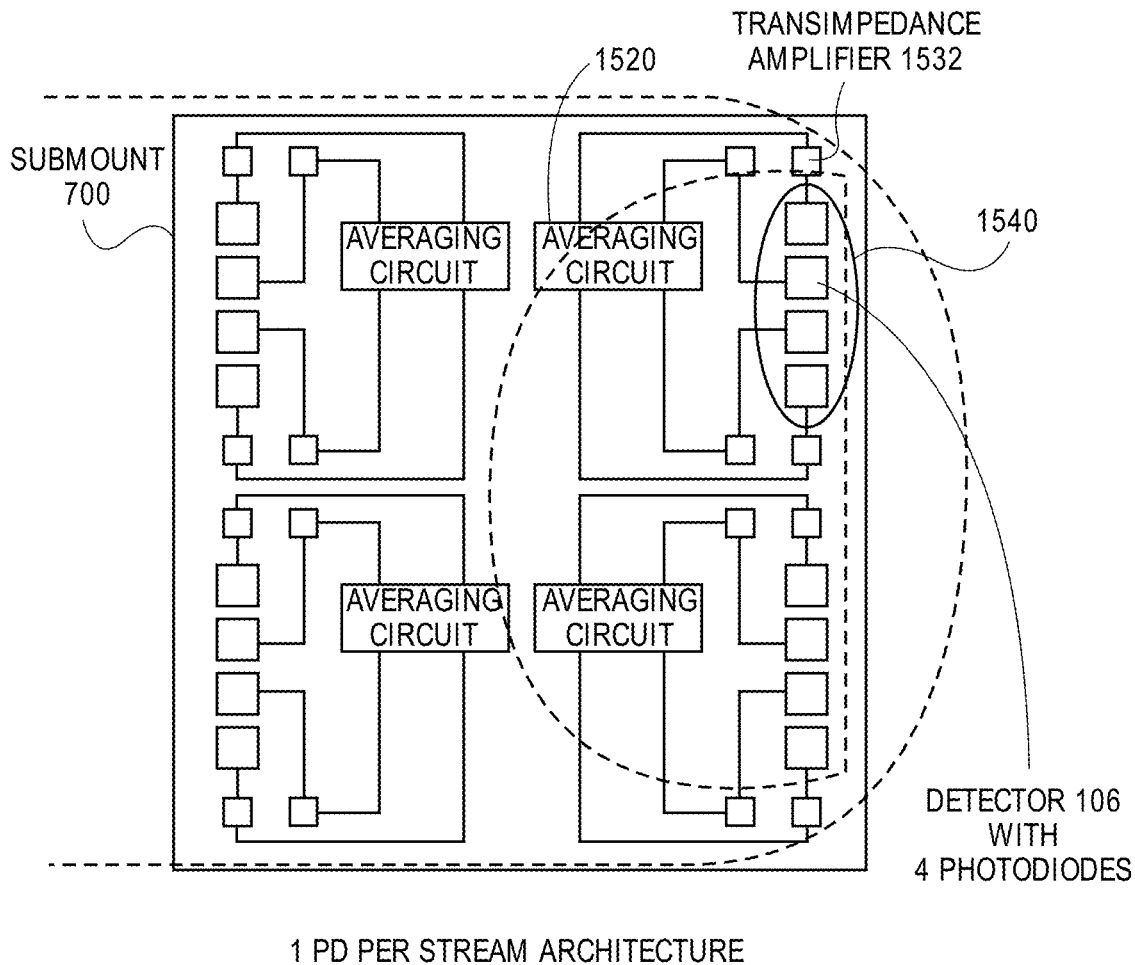
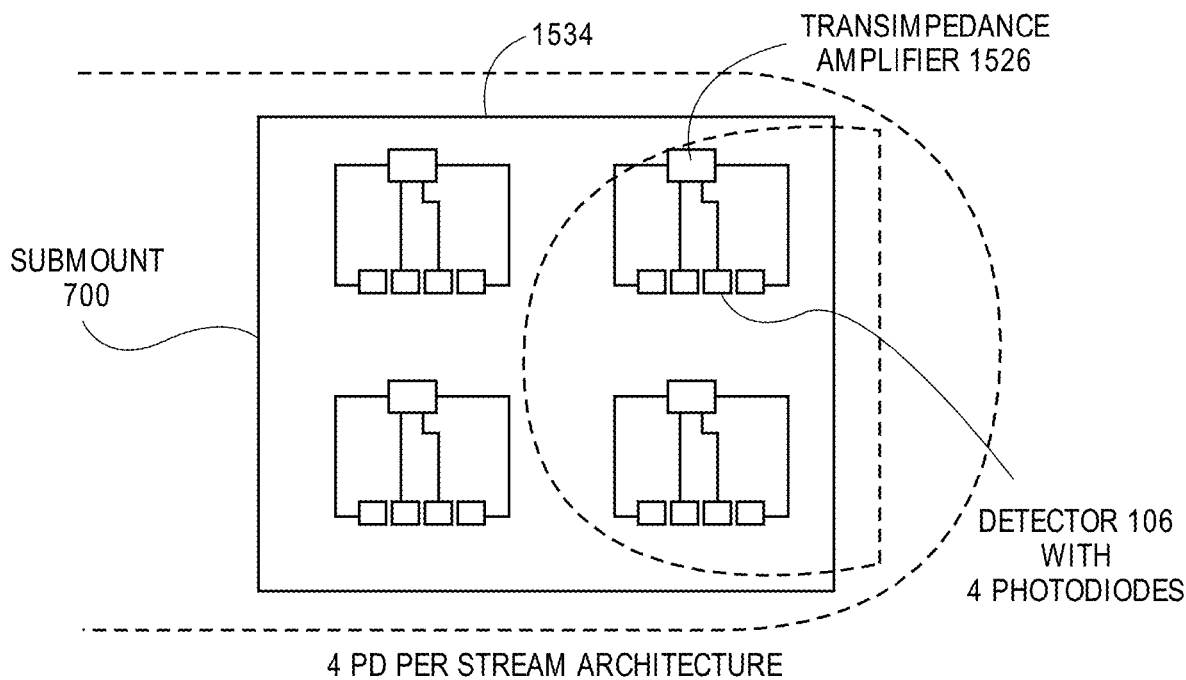


FIG. 15K (CONT.)

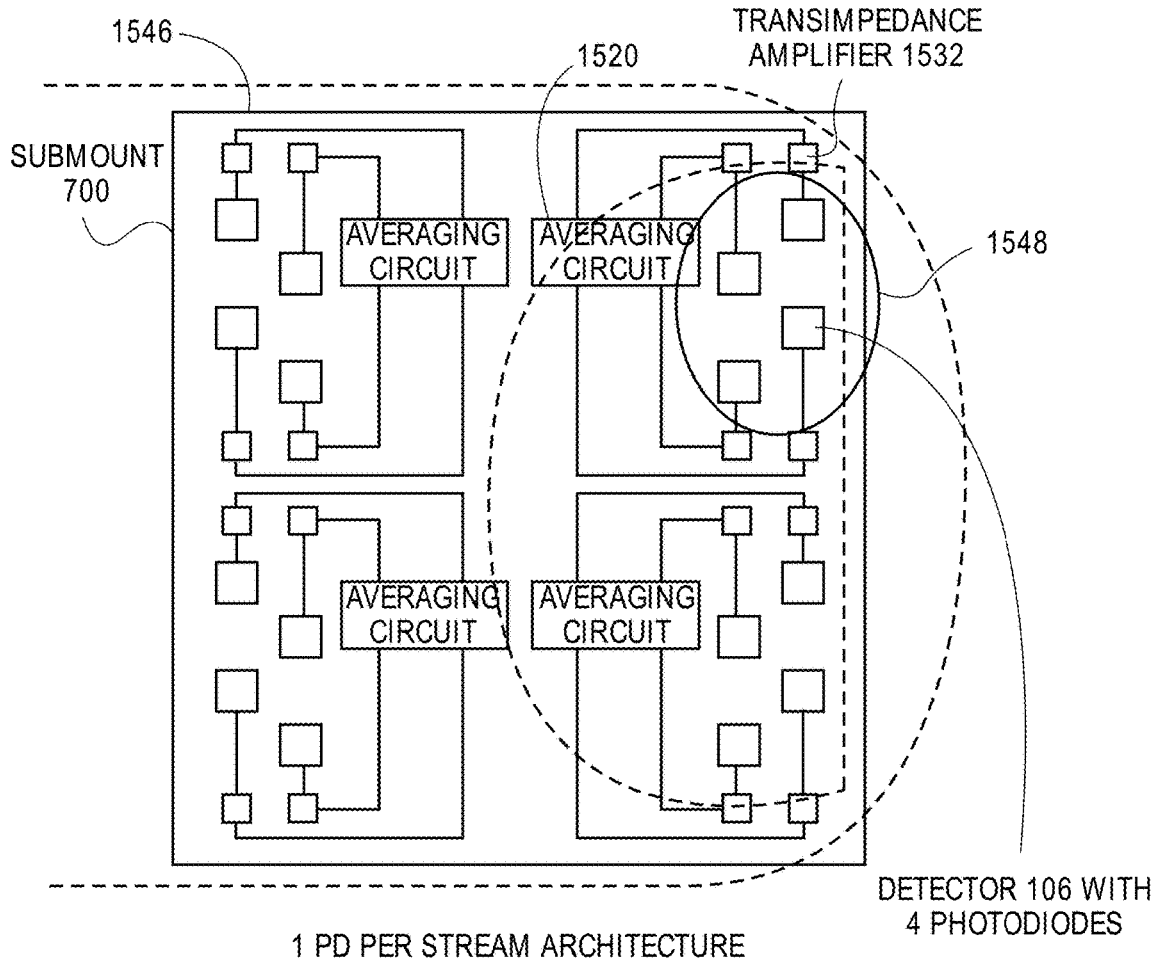
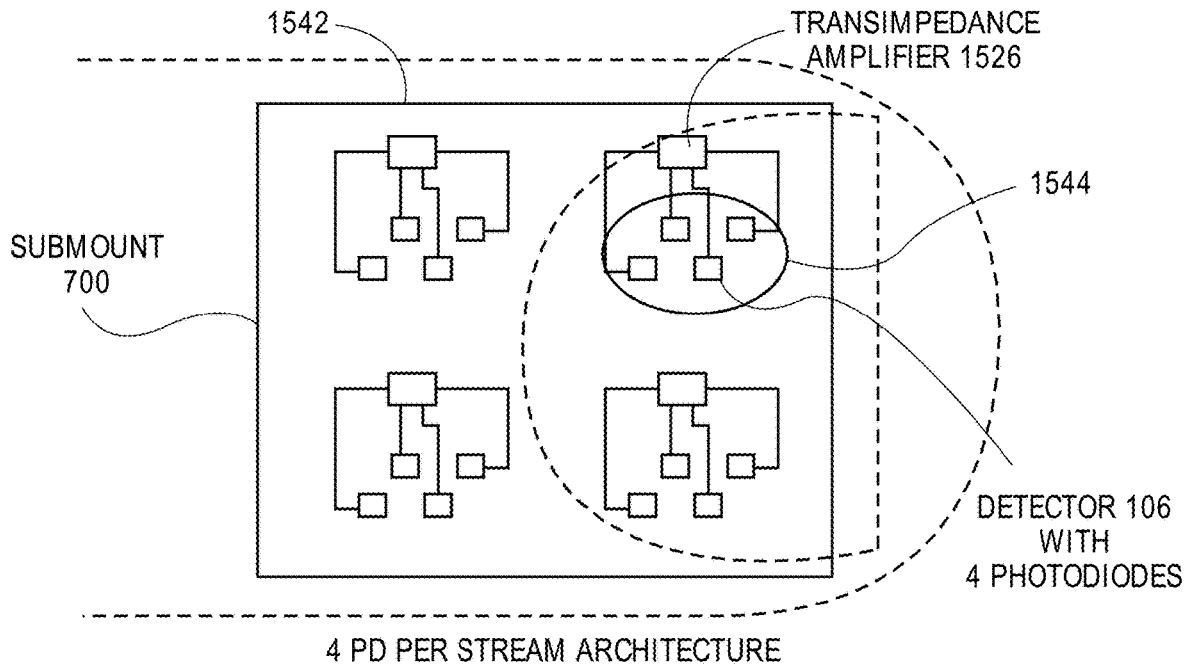


FIG. 15K (CONT.)

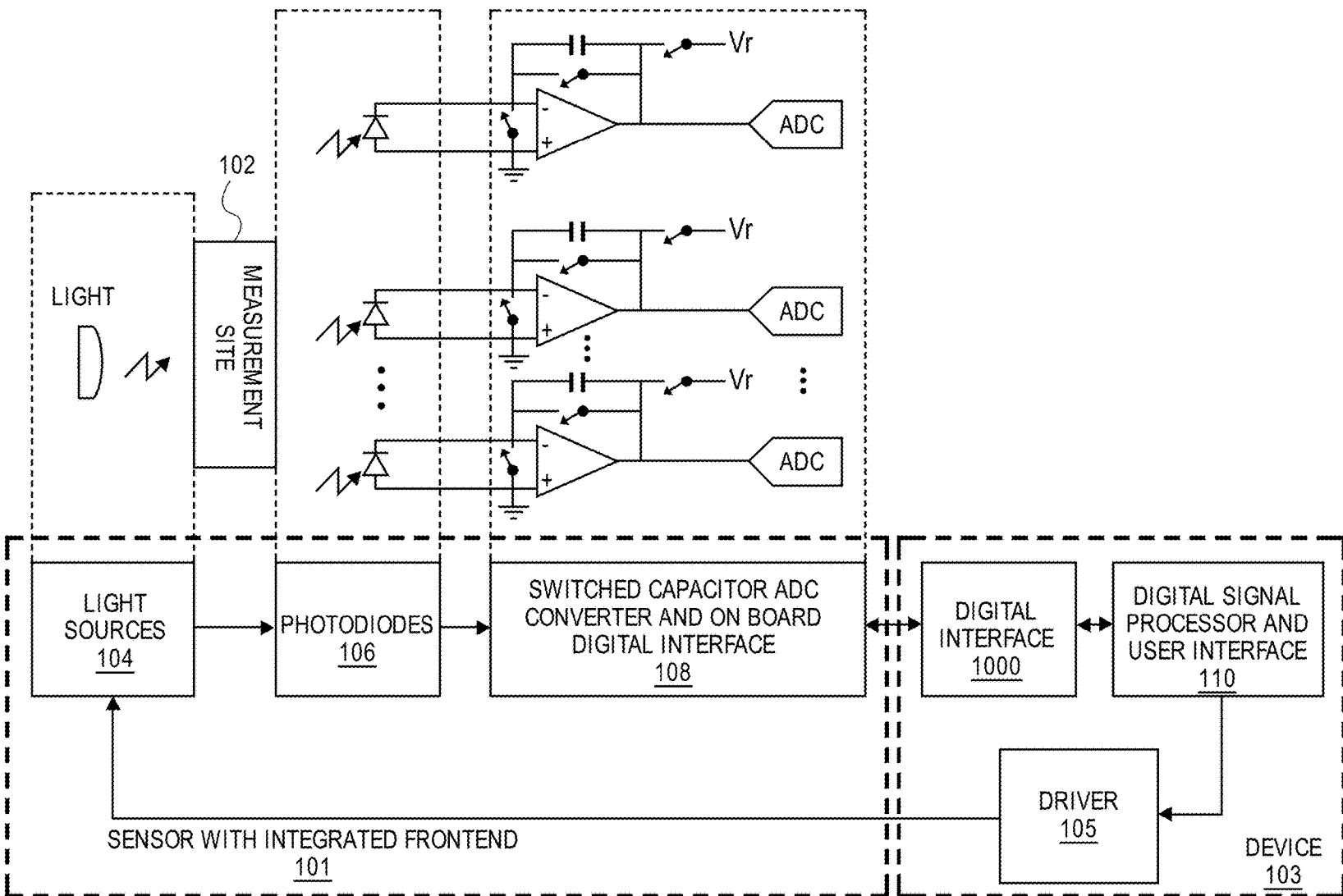


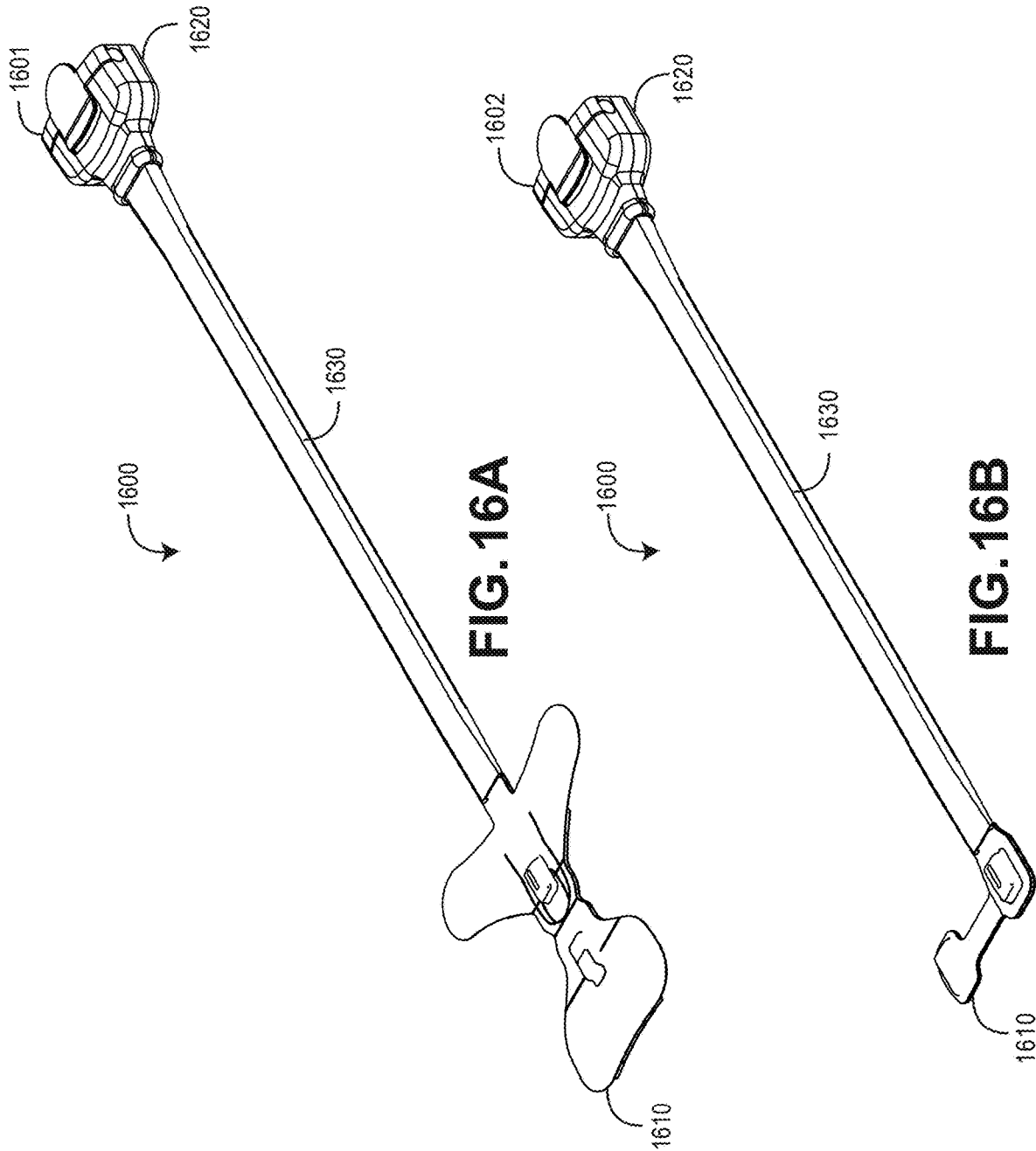
FIG. 15L

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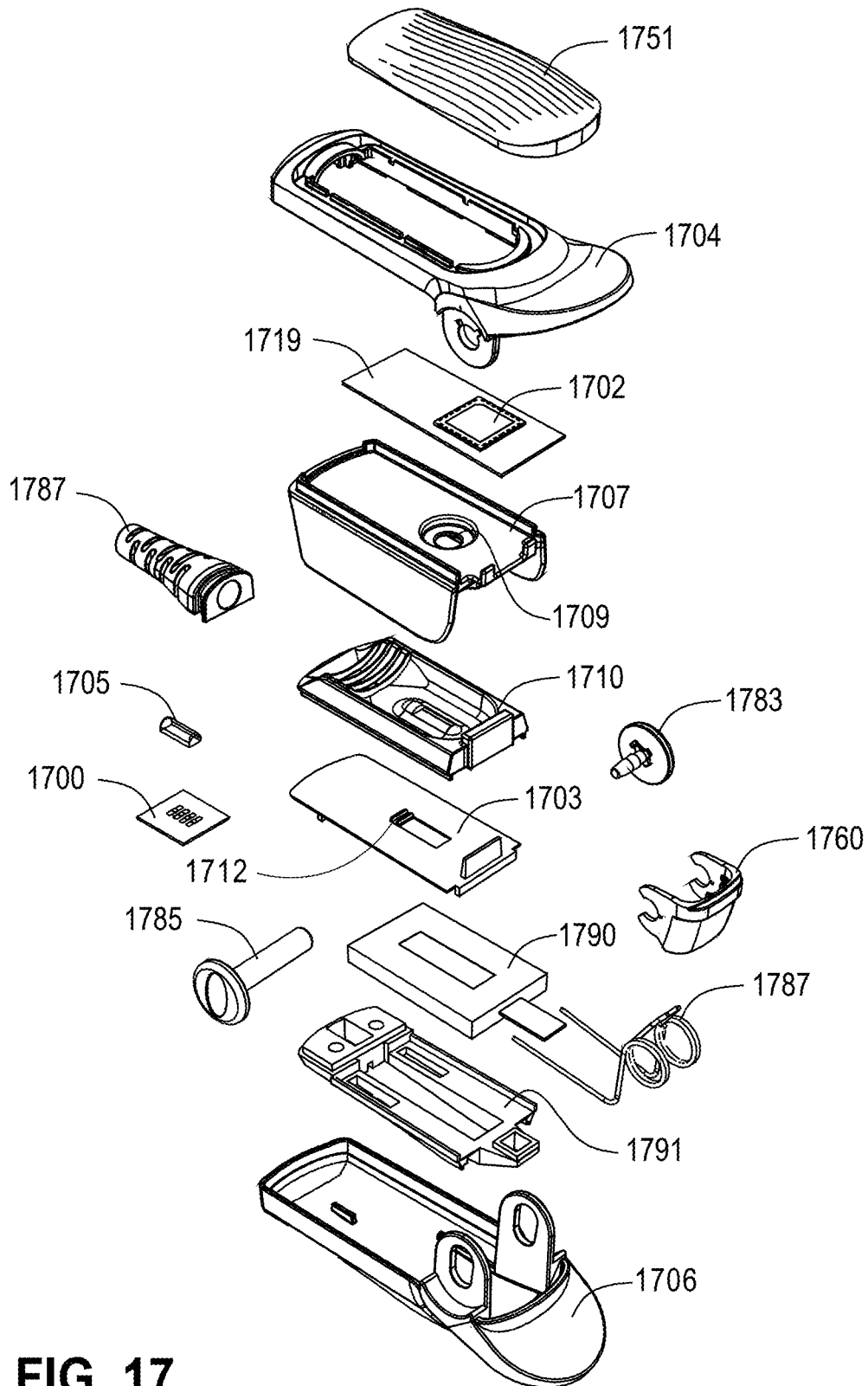
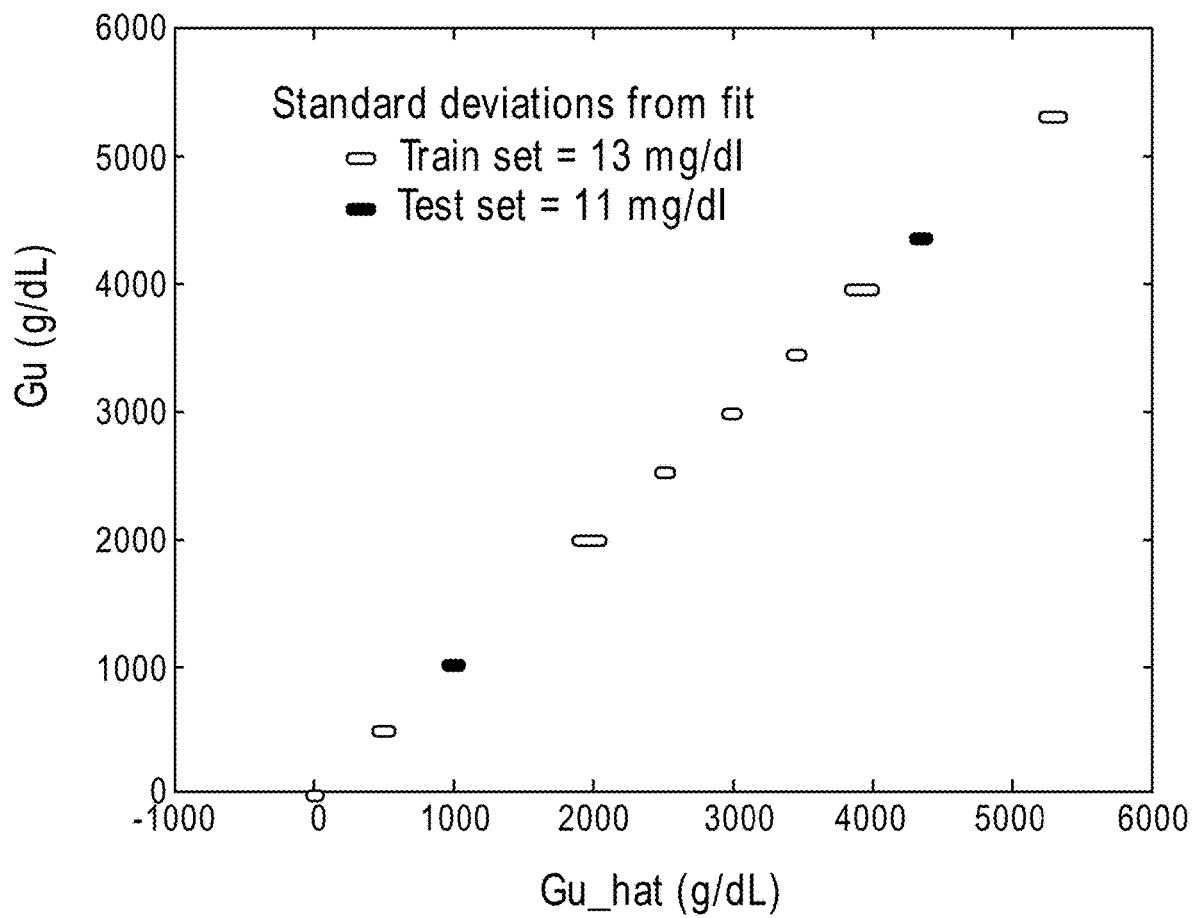


FIG. 17

**FIG. 18**

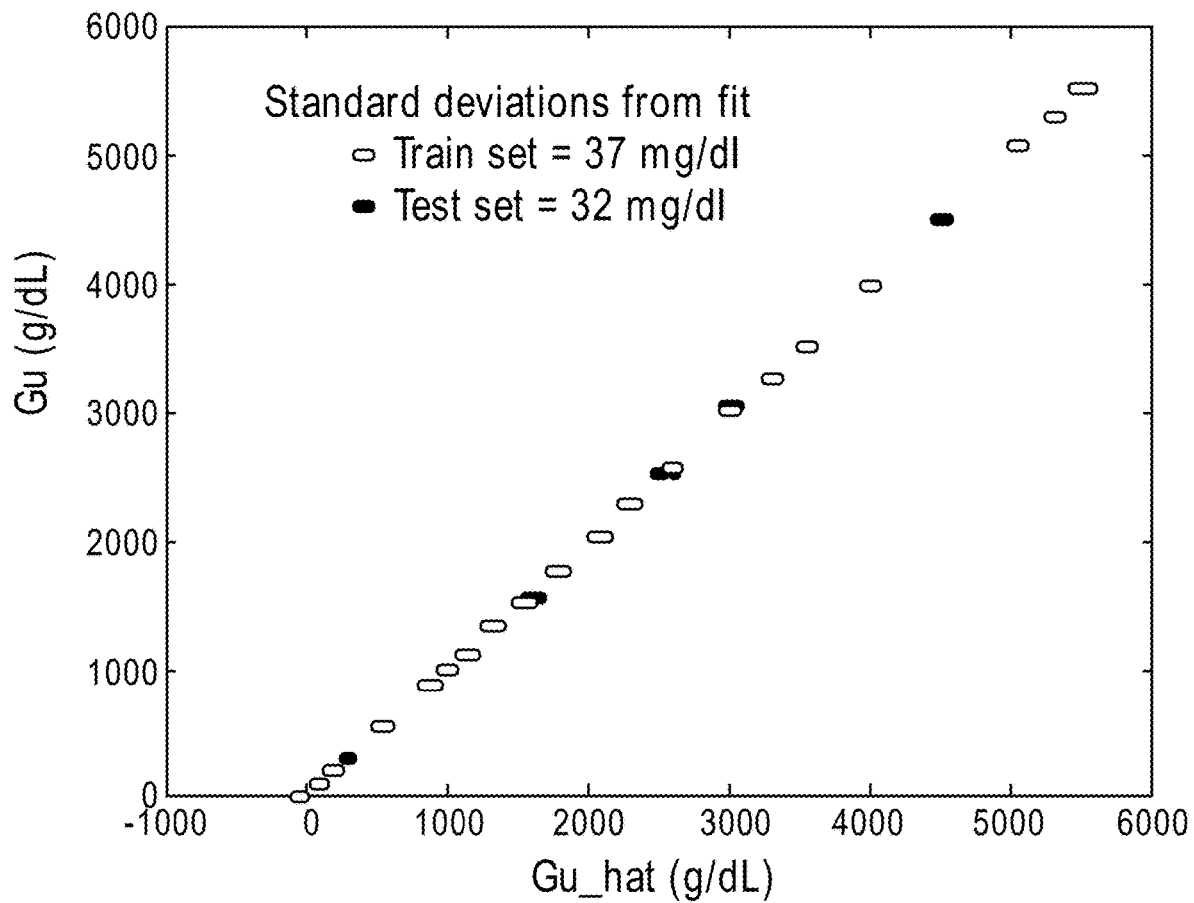


FIG. 19

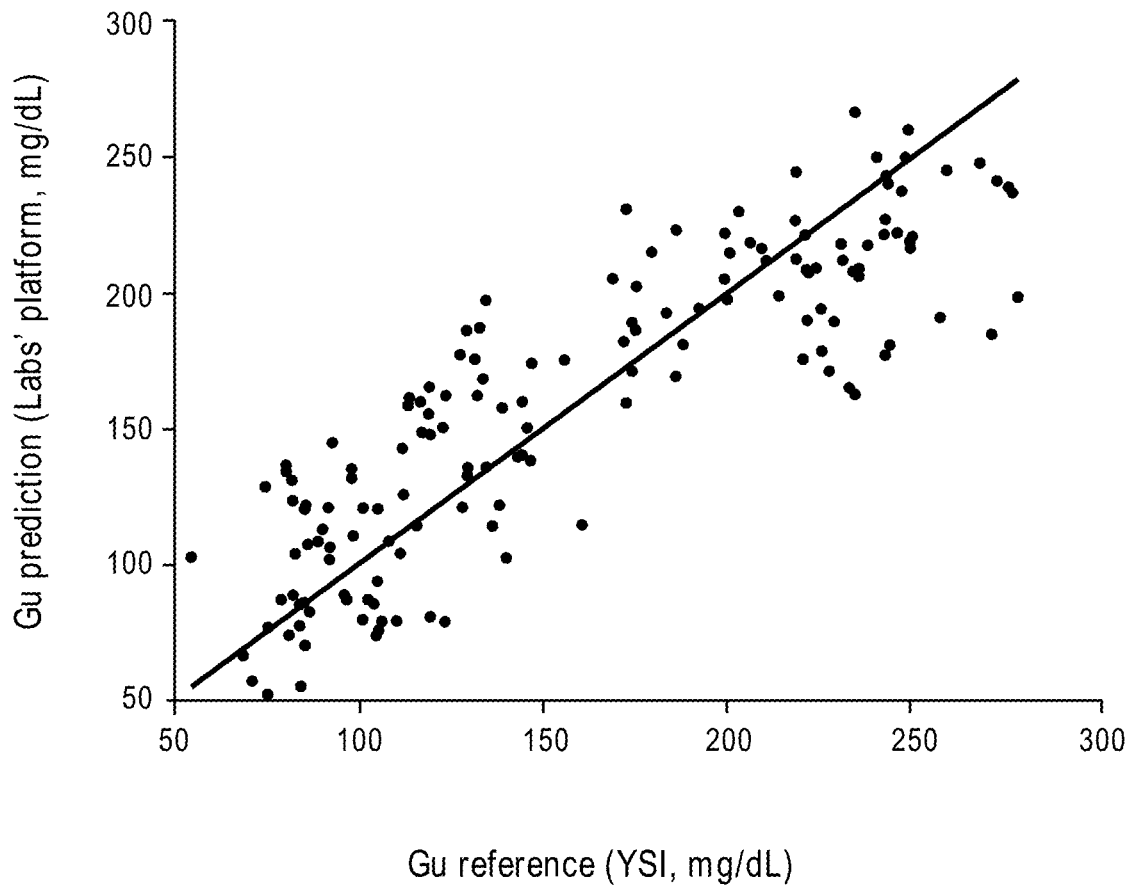


FIG. 20

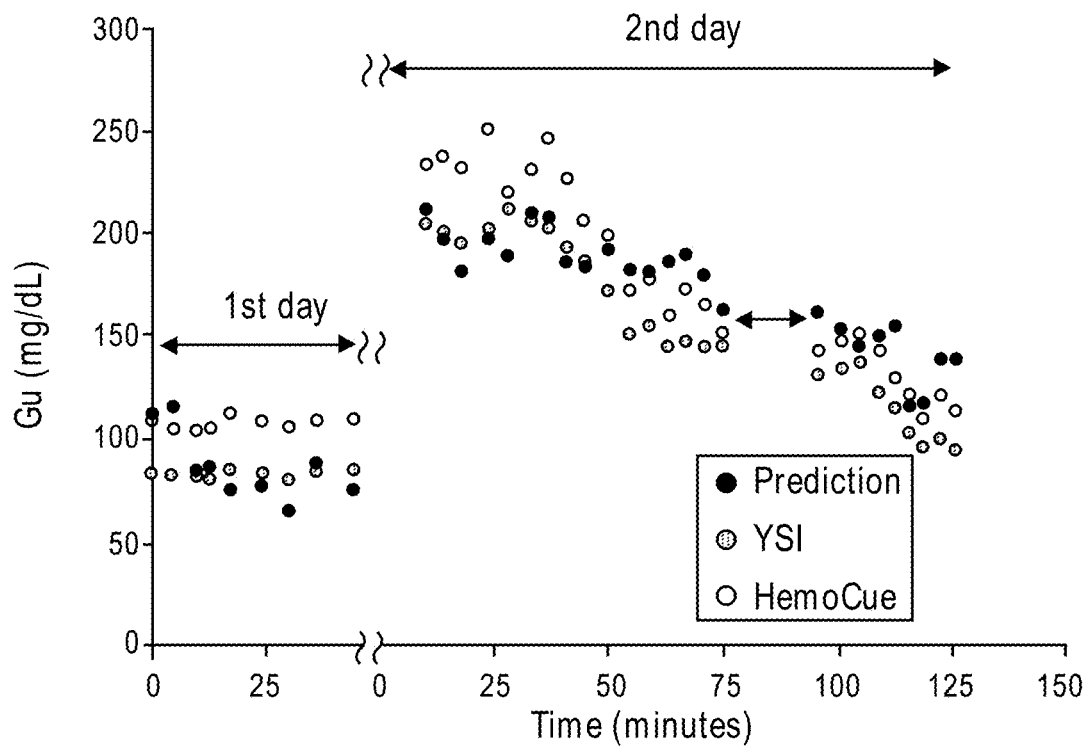


FIG. 21

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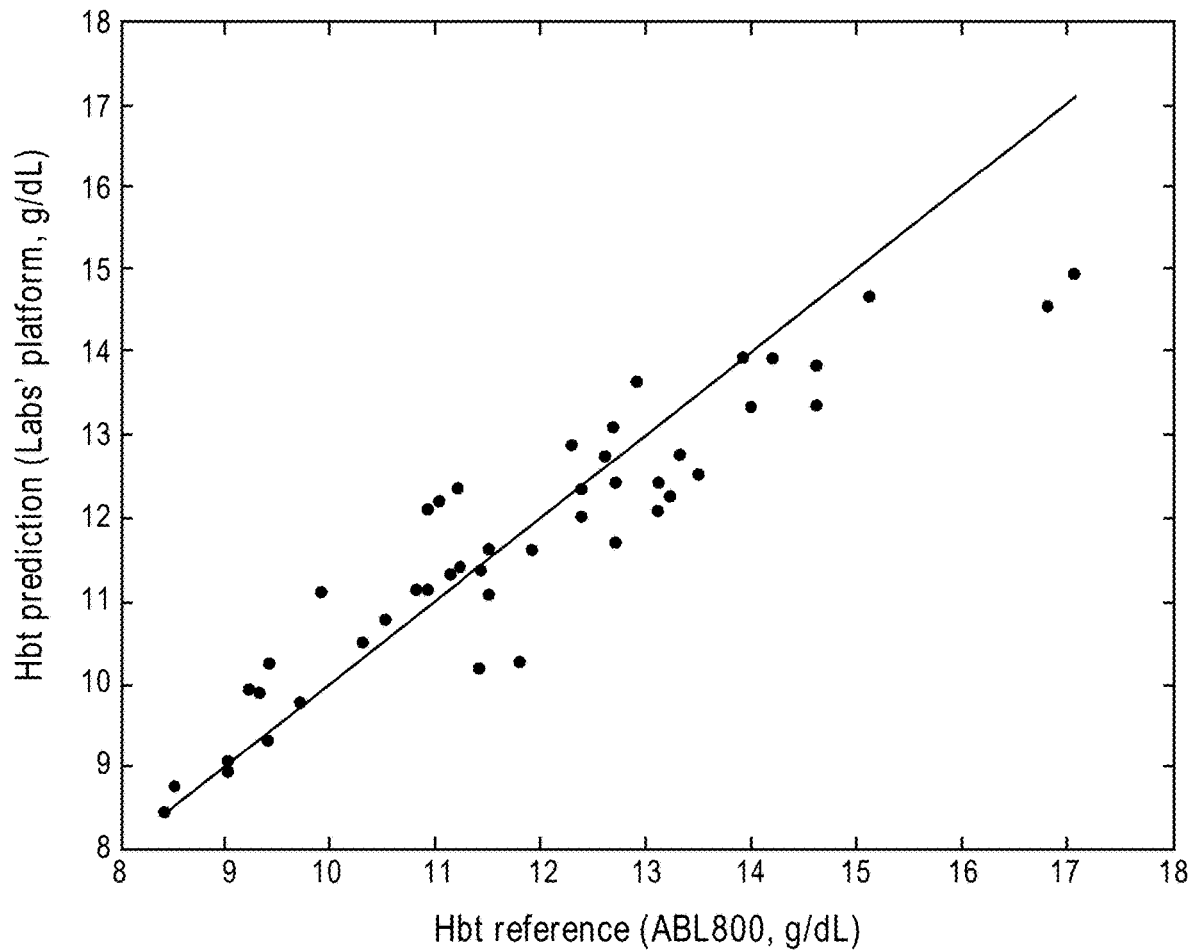


FIG. 22

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MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/725,292, filed Dec. 23, 2019, which is a continuation of U.S. patent application Ser. No. 16/534,949, filed Aug. 7, 2019, which is a continuation of U.S. patent application Ser. No. 16/409,515, filed May 10, 2019, which is a continuation of U.S. patent application Ser. No. 16/261,326, filed Jan. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/212,537, filed Dec. 6, 2018, which is a continuation of U.S. patent application Ser. No. 14/981,290 filed Dec. 28, 2015, which is a continuation of U.S. patent application Ser. No. 12/829,352 filed Jul. 1, 2010, which is a continuation of U.S. patent application Ser. No. 12/534,827 filed Aug. 3, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,528 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,528 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Nos. 29/323,409 filed Aug. 25, 2008 and 29/323,408 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/829,352 is also a continuation-in-part of U.S. patent application Ser. No. 12/497,523 filed Jul. 2, 2009, which claims the benefit of priority under 35 U.S.C. § 119(e) of the following U.S. Provisional Patent Application Nos. 61/086,060 filed Aug. 4, 2008, 61/086,108 filed Aug. 4, 2008, 61/086,063 filed Aug. 4, 2008, 61/086,057 filed Aug. 4, 2008, 61/078,228 filed Jul. 3, 2008, 61/078,207 filed Jul. 3, 2008, and 61/091,732 filed Aug. 25, 2008. U.S. patent application Ser. No. 12/497,523 also claims the benefit of priority under 35 U.S.C. § 120 as a continuation-in-part of the following U.S. Design patent application Nos. 29/323,409 filed Aug. 25, 2008 and 29/323,408 filed Aug. 25, 2008.

This application is related to the following U.S. Patent Applications:

App. No.	Filing Date	Title
12/497,528	Jul. 2, 2009	Noise Shielding for Noninvasive Device
12/497,523	Jul. 2, 2009	Contoured Protrusion for Improving Spectroscopic Measurement of Blood Constituents
12/497,506	Jul. 2, 2009	Heat Sink for Noninvasive Medical Sensor
12/534,812	Aug. 3, 2009	Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents
12/534,823	Aug. 3, 2009	Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents
12/534,825	Aug. 3, 2009	Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents

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The foregoing applications are hereby incorporated by reference in their entirety.

BACKGROUND

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The standard of care in caregiver environments includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Devices capable of spectroscopic analysis generally include a light source(s) transmitting optical radiation into or reflecting off a measurement site, such as, body tissue carrying pulsing blood. After attenuation by tissue and fluids of the measurement site, a photo-detection device(s) detects the attenuated light and outputs a detector signal(s) responsive to the detected attenuated light. A signal processing device(s) process the detector(s) signal (s) and outputs a measurement indicative of a blood constituent of interest, such as glucose, oxygen, met hemoglobin, total hemoglobin, other physiological parameters, or other data or combinations of data useful in determining a state or trend of wellness of a patient.

In noninvasive devices and methods, a sensor is often adapted to position a finger proximate the light source and light detector. For example, noninvasive sensors often include a clothespin-shaped housing that includes a contoured bed conforming generally to the shape of a finger.

SUMMARY

This disclosure describes embodiments of noninvasive methods, devices, and systems for measuring a blood constituent or analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate, for example, to pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, the system includes a noninvasive sensor and a patient monitor communicating with the non-invasive sensor. The non-invasive sensor may include different architectures to implement some or all of the disclosed features. In addition, an artisan will recognize that the non-invasive sensor may include or may be coupled to other components, such as a network interface, and the like. Moreover, the patient monitor may include a display device, a network interface communicating with any one or combination of a computer network, a handheld computing device, a mobile phone, the Internet, or the like. In addition, embodiments may include multiple optical sources that emit light at a plurality of wavelengths and that are arranged from the perspective of the light detector(s) as a point source.

In an embodiment, a noninvasive device is capable of producing a signal responsive to light attenuated by tissue at a measurement site. The device may comprise an optical source and a plurality of photodetectors. The optical source is configured to emit optical radiation at least at wavelengths between about 1600 nm and about 1700 nm. The photodetectors are configured to detect the optical radiation from said optical source after attenuation by the tissue of the measurement site and each output a respective signal stream responsive to the detected optical radiation.

In an embodiment, a noninvasive, physiological sensor is capable of outputting a signal responsive to a blood analyte present in a monitored patient. The sensor may comprise a sensor housing, an optical source, and photodetectors. The optical source is positioned by the housing with respect to a tissue site of a patient when said housing is applied to the

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patient. The photodetectors are positioned by the housing with respect to said tissue site when the housing is applied to the patient with a variation in path length among at least some of the photodetectors from the optical source. The photodetectors are configured to detect a sequence of optical radiation from the optical source after attenuation by tissue of the tissue site. The photodetectors may be each configured to output a respective signal stream responsive to the detected sequence of optical radiation. An output signal responsive to one or more of the signal streams is then usable to determine the blood analyte based at least in part on the variation in path length.

In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the

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multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient

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power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. 1 illustrates a block diagram of an example data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure;

FIGS. 2A-2D illustrate an exemplary handheld monitor and an exemplary noninvasive optical sensor of the patient monitoring system of FIG. 1, according to embodiments of the disclosure;

FIGS. 3A-3C illustrate side and perspective views of an exemplary noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIG. 3D illustrates a side view of another example non-invasive sensor housing including a heat sink, according to an embodiment of the disclosure;

FIG. 3E illustrates a perspective view of an example noninvasive sensor detector shell including example detectors, according to an embodiment of the disclosure;

FIG. 3F illustrates a side view of an example noninvasive sensor housing including a finger bed protrusion and heat sink, according to an embodiment of the disclosure;

FIGS. 4A through 4C illustrate top elevation, side and top perspective views of an example protrusion, according to an embodiment of the disclosure;

FIG. 5 illustrates an example graph depicting possible effects of a protrusion on light transmittance, according to an embodiment of the disclosure;

FIGS. 6A through 6D illustrate perspective, front elevation, side and top views of another example protrusion, according to an embodiment of the disclosure;

FIG. 6E illustrates an example sensor incorporating the protrusion of FIGS. 6A through 6D, according to an embodiment of the disclosure;

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FIGS. 7A through 7B illustrate example arrangements of conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIGS. 8A through 8D illustrate an example top elevation view, side views, and a bottom elevation view of the conductive glass that may be employed in the system of FIG. 1, according to embodiments of the disclosure;

FIG. 9 shows example comparative results obtained by an embodiment of a sensor;

FIGS. 10A and 10B illustrate comparative noise floors of various embodiments of the present disclosure;

FIG. 11A illustrates an exemplary emitter that may be employed in the sensor, according to an embodiment of the disclosure;

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring blood constituents, according to an embodiment of the disclosure;

FIG. 11C illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 11D illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure;

FIG. 12A illustrates an example detector portion that may be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIGS. 12B through 12D illustrate exemplary arrangements of detectors that may be employed in an embodiment of the sensor, according to some embodiments of the disclosure;

FIGS. 12E through 12H illustrate exemplary structures of photodiodes that may be employed in embodiments of the detectors, according to some embodiments of the disclosure;

FIG. 13 illustrates an example multi-stream operation of the system of FIG. 1, according to an embodiment of the disclosure;

FIG. 14A illustrates another example detector portion having a partially cylindrical protrusion that can be employed in an embodiment of a sensor, according to an embodiment of the disclosure;

FIG. 14B depicts a front elevation view of the partially cylindrical protrusion of FIG. 14A;

FIGS. 14C through 14E illustrate embodiments of a detector submount;

FIGS. 14F through 14H illustrate embodiment of portions of a detector shell;

FIG. 14I illustrates a cutaway view of an embodiment of a sensor;

FIGS. 15A through 15F illustrate embodiments of sensors that include heat sink features;

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described herein;

FIG. 15I illustrates an exemplary architecture for a transimpedance-based front-end that may be employed in any of the sensors described herein;

FIG. 15J illustrates an exemplary noise model for configuring the transimpedance-based front-ends shown in FIG. 15I;

FIG. 15K shows different architectures and layouts for various embodiments of a sensor and its detectors;

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end that may be employed in any of the sensors described herein;

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors;

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FIG. 17 illustrates an exploded view of certain components of an example sensor; and

FIGS. 18 through 22 illustrate various results obtained by an exemplary sensor of the disclosure.

DETAILED DESCRIPTION

The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens

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made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of non-invasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metallicized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

The sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter can include a plurality of sets of optical sources that, in an embodiment, are arranged together as a point source. The various optical sources can emit a sequence of optical radiation pulses at different wavelengths towards a measurement site, such as a patient's finger. Detectors can then detect optical radiation from the measurement site. The optical sources and optical radiation detectors can operate at

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any appropriate wavelength, including, as discussed herein, infrared, near infrared, visible light, and ultraviolet. In addition, the optical sources and optical radiation detectors can operate at any appropriate wavelength, and such modifications to the embodiments desirable to operate at any such wavelength will be apparent to those skilled in the art.

In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

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The sensor can be coupled to one or more monitors that process and/or display the sensor's output. The monitors can include various components, such as a sensor front end, a signal processor, a display, etc.

The sensor can be integrated with a monitor, for example, into a handheld unit including the sensor, a display and user controls. In other embodiments, the sensor can communicate with one or more processing devices. The communication can be via wire(s), cable(s), flex circuit(s), wireless technologies, or other suitable analog or digital communication methodologies and devices to perform those methodologies. Many of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on a patient, such as the patient's arm, or placed at a location near the patient, such as a bed, shelf or table. The sensor or monitor can also provide outputs to a storage device or network interface.

Reference will now be made to the Figures to discuss embodiments of the present disclosure.

FIG. 1 illustrates an example of a data collection system 100. In certain embodiments, the data collection system 100 noninvasively measure a blood analyte, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics. The system 100 can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The data collection system 100 can be capable of measuring optical radiation from the measurement site. For example, in some embodiments, the data collection system 100 can employ photodiodes defined in terms of area. In an embodiment, the area is from about 1 mm²-5 mm² (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. In addition to having its ordinary meaning, the phrase "at full scale" can mean light saturation of a photodiode amplifier (not shown). Of course, as would be understood by a person of skill in the art from the present disclosure, various other sizes and types of photodiodes can be used with the embodiments of the present disclosure.

The data collection system 100 can measure a range of approximately about 2 nA to about 100 nA full scale. The data collection system 100 can also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100 decibels (dB) or more, such as about 120 dB in order to measure various desired analytes. The data collection system 100 can operate with a lower SNR if less accuracy is desired for an analyte like glucose.

The data collection system 100 can measure analyte concentrations, including glucose, at least in part by detecting light attenuated by a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, ear lobe, or the like. For convenience, this disclosure is described primarily in the context of a finger measurement site 102. However, the features of the embodiments disclosed herein can be used with other measurement sites 102.

In the depicted embodiment, the system 100 includes an optional tissue thickness adjuster or tissue shaper 105, which can include one or more protrusions, bumps, lenses, or other suitable tissue-shaping mechanisms. In certain embodiments, the tissue shaper 105 is a flat or substantially flat surface that can be positioned proximate the measurement site 102 and that can apply sufficient pressure to cause the

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tissue of the measurement site **102** to be flat or substantially flat. In other embodiments, the tissue shaper **105** is a convex or substantially convex surface with respect to the measurement site **102**. Many other configurations of the tissue shaper **105** are possible. Advantageously, in certain embodiments, the tissue shaper **105** reduces thickness of the measurement site **102** while preventing or reducing occlusion at the measurement site **102**. Reducing thickness of the site can advantageously reduce the amount of attenuation of the light because there is less tissue through which the light must travel. Shaping the tissue in to a convex (or alternatively concave) surface can also provide more surface area from which light can be detected.

The embodiment of the data collection system **100** shown also includes an optional noise shield **103**. In an embodiment, the noise shield **103** can be advantageously adapted to reduce electromagnetic noise while increasing the transmittance of light from the measurement site **102** to one or more detectors **106** (described below). For example, the noise shield **103** can advantageously include a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor **101** or electrically grounded. In an embodiment where the noise shield **103** includes conductive coated glass, the coating can advantageously include indium tin oxide. In an embodiment, the indium tin oxide includes a surface resistivity ranging from approximately 30 ohms per square inch to about 500 ohms per square inch. In an embodiment, the resistivity is approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than about 30 ohms or more than about 500 ohms. Other conductive materials transparent or substantially transparent to light can be used instead.

In some embodiments, the measurement site **102** is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand. In some patients, the non-dominant arm or hand can have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content can provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose. Accordingly, in some embodiments, the data collection system **100** can be used on a person's non-dominant hand or arm.

The data collection system **100** can include a sensor **101** (or multiple sensors) that is coupled to a processing device or physiological monitor **109**. In an embodiment, the sensor **101** and the monitor **109** are integrated together into a single unit. In another embodiment, the sensor **101** and the monitor **109** are separate from each other and communicate one with another in any suitable manner, such as via a wired or wireless connection. The sensor **101** and monitor **109** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. The sensor **101** and the monitor **109** will now be further described.

In the depicted embodiment shown in FIG. 1, the sensor **101** includes an emitter **104**, a tissue shaper **105**, a set of detectors **106**, and a front-end interface **108**. The emitter **104** can serve as the source of optical radiation transmitted towards measurement site **102**. As will be described in further detail below, the emitter **104** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodi-

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ment, the emitter **104** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

In some embodiments, the emitter **104** is used as a point optical source, and thus, the one or more optical sources of the emitter **104** can be located within a close distance to each other, such as within about a 2 mm to about 4 mm. The emitters **104** can be arranged in an array, such as is described in U.S. Publication No. 2006/0211924, filed Sep. 21, 2006, titled "Multiple Wavelength Sensor Emitters," the disclosure of which is hereby incorporated by reference in its entirety. In particular, the emitters **104** can be arranged at least in part as described in paragraphs [0061] through [0068] of the aforementioned publication, which paragraphs are hereby incorporated specifically by reference. Other relative spatial relationships can be used to arrange the emitters **104**.

For analytes like glucose, currently available non-invasive techniques often attempt to employ light near the water absorbance minima at or about 1600 nm. Typically, these devices and methods employ a single wavelength or single band of wavelengths at or about 1600 nm. However, to date, these techniques have been unable to adequately consistently measure analytes like glucose based on spectroscopy.

In contrast, the emitter **104** of the data collection system **100** can emit, in certain embodiments, combinations of optical radiation in various bands of interest. For example, in some embodiments, for analytes like glucose, the emitter **104** can emit optical radiation at three (3) or more wavelengths between about 1600 nm to about 1700 nm. In particular, the emitter **104** can emit optical radiation at or about 1610 nm, about 1640 nm, and about 1665 nm. In some circumstances, the use of three wavelengths within about 1600 nm to about 1700 nm enable sufficient SNRs of about 100 dB, which can result in a measurement accuracy of about 20 mg/dL or better for analytes like glucose.

In other embodiments, the emitter **104** can use two (2) wavelengths within about 1600 nm to about 1700 nm to advantageously enable SNRs of about 85 dB, which can result in a measurement accuracy of about 25-30 mg/dL or better for analytes like glucose. Furthermore, in some embodiments, the emitter **104** can emit light at wavelengths above about 1670 nm. Measurements at these wavelengths can be advantageously used to compensate or confirm the contribution of protein, water, and other non-hemoglobin species exhibited in measurements for analytes like glucose conducted between about 1600 nm and about 1700 nm. Of course, other wavelengths and combinations of wavelengths can be used to measure analytes and/or to distinguish other types of tissue, fluids, tissue properties, fluid properties, combinations of the same or the like.

For example, the emitter **104** can emit optical radiation across other spectra for other analytes. In particular, the emitter **104** can employ light wavelengths to measure various blood analytes or percentages (e.g., saturation) thereof. For example, in one embodiment, the emitter **104** can emit optical radiation in the form of pulses at wavelengths about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter **104** can emit optical radiation ranging from about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, the emitter **104** can transmit any of a variety of wavelengths of visible or near-infrared optical radiation.

Due to the different responses of analytes to the different wavelengths, certain embodiments of the data collection

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system **100** can advantageously use the measurements at these different wavelengths to improve the accuracy of measurements. For example, the measurements of water from visible and infrared light can be used to compensate for water absorbance that is exhibited in the near-infrared wavelengths.

As briefly described above, the emitter **104** can include sets of light-emitting diodes (LEDs) as its optical source. The emitter **104** can use one or more top-emitting LEDs. In particular, in some embodiments, the emitter **104** can include top-emitting LEDs emitting light at about 850 nm to 1350 nm.

The emitter **104** can also use super luminescent LEDs (SLEDs) or side-emitting LEDs. In some embodiments, the emitter **104** can employ SLEDs or side-emitting LEDs to emit optical radiation at about 1600 nm to about 1800 nm. Emitter **104** can use SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power, e.g., about 40 mW to about 100 mW. This higher power capability can be useful to compensate or overcome the greater attenuation of these wavelengths of light in tissue and water. For example, the higher power emission can effectively compensate and/or normalize the absorption signal for light in the mentioned wavelengths to be similar in amplitude and/or effect as other wavelengths that can be detected by one or more photodetectors after absorption. However, the embodiments of the present disclosure do not necessarily require the use of high power optical sources. For example, some embodiments may be configured to measure analytes, such as total hemoglobin (tHb), oxygen saturation (SpO₂), carboxyhemoglobin, methemoglobin, etc., without the use of high power optical sources like side emitting LEDs. Instead, such embodiments may employ other types of optical sources, such as top emitting LEDs. Alternatively, the emitter **104** can use other types of sources of optical radiation, such as a laser diode, to emit near-infrared light into the measurement site **102**.

In addition, in some embodiments, in order to assist in achieving a comparative balance of desired power output between the LEDs, some of the LEDs in the emitter **104** can have a filter or covering that reduces and/or cleans the optical radiation from particular LEDs or groups of LEDs. For example, since some wavelengths of light can penetrate through tissue relatively well, LEDs, such as some or all of the top-emitting LEDs can use a filter or covering, such as a cap or painted dye. This can be useful in allowing the emitter **104** to use LEDs with a higher output and/or to equalize intensity of LEDs.

The data collection system **100** also includes a driver **111** that drives the emitter **104**. The driver **111** can be a circuit or the like that is controlled by the monitor **109**. For example, the driver **111** can provide pulses of current to the emitter **104**. In an embodiment, the driver **111** drives the emitter **104** in a progressive fashion, such as in an alternating manner. The driver **111** can drive the emitter **104** with a series of pulses of about 1 milliwatt (mW) for some wavelengths that can penetrate tissue relatively well and from about 40 mW to about 100 mW for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments.

The driver **111** can be synchronized with other parts of the sensor **101** and can minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **104**. In some embodiments, the driver **111** is capable of driving the

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emitter **104** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detectors **106** capture and measure light from the measurement site **102**. For example, the detectors **106** can capture and measure light transmitted from the emitter **104** that has been attenuated or reflected from the tissue in the measurement site **102**. The detectors **106** can output a detector signal **107** responsive to the light captured or measured. The detectors **106** can be implemented using one or more photodiodes, phototransistors, or the like.

In addition, the detectors **106** can be arranged with a spatial configuration to provide a variation of path lengths among at least some of the detectors **106**. That is, some of the detectors **106** can have the substantially, or from the perspective of the processing algorithm, effectively, the same path length from the emitter **104**. However, according to an embodiment, at least some of the detectors **106** can have a different path length from the emitter **104** relative to other of the detectors **106**. Variations in path lengths can be helpful in allowing the use of a bulk signal stream from the detectors **106**. In some embodiments, the detectors **106** may employ a linear spacing, a logarithmic spacing, or a two or three dimensional matrix of spacing, or any other spacing scheme in order to provide an appropriate variation in path lengths.

The front end interface **108** provides an interface that adapts the output of the detectors **106**, which is responsive to desired physiological parameters. For example, the front end interface **108** can adapt a signal **107** received from one or more of the detectors **106** into a form that can be processed by the monitor **109**, for example, by a signal processor **110** in the monitor **109**. The front end interface **108** can have its components assembled in the sensor **101**, in the monitor **109**, in connecting cabling (if used), combinations of the same, or the like. The location of the front end interface **108** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front end interface **108** can be coupled to the detectors **106** and to the signal processor **110** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front end interface **108** can also be at least partially integrated with various components, such as the detectors **106**. For example, the front end interface **108** can include one or more integrated circuits that are on the same circuit board as the detectors **106**. Other configurations can also be used.

The front end interface **108** can be implemented using one or more amplifiers, such as transimpedance amplifiers, that are coupled to one or more analog to digital converters (ADCs) (which can be in the monitor **109**), such as a sigma-delta ADC. A transimpedance-based front end interface **108** can employ single-ended circuitry, differential circuitry, and/or a hybrid configuration. A transimpedance-based front end interface **108** can be useful for its sampling rate capability and freedom in modulation/demodulation algorithms. For example, this type of front end interface **108** can advantageously facilitate the sampling of the ADCs being synchronized with the pulses emitted from the emitter **104**.

The ADC or ADCs can provide one or more outputs into multiple channels of digital information for processing by the signal processor **110** of the monitor **109**. Each channel can correspond to a signal output from a detector **106**.

In some embodiments, a programmable gain amplifier (PGA) can be used in combination with a transimpedance-based front end interface **108**. For example, the output of a

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transimpedance-based front end interface **108** can be output to a PGA that is coupled with an ADC in the monitor **109**. A PGA can be useful in order to provide another level of amplification and control of the stream of signals from the detectors **106**. Alternatively, the PGA and ADC components

can be integrated with the transimpedance-based front end interface **108** in the sensor **101**.
In another embodiment, the front end interface **108** can be implemented using switched-capacitor circuits. A switched-capacitor-based front end interface **108** can be useful for, in certain embodiments, its resistor-free design and analog averaging properties. In addition, a switched-capacitor-based front end interface **108** can be useful because it can provide a digital signal to the signal processor **110** in the monitor **109**.

As shown in FIG. 1, the monitor **109** can include the signal processor **110** and a user interface, such as a display **112**. The monitor **109** can also include optional outputs alone or in combination with the display **112**, such as a storage device **114** and a network interface **116**. In an embodiment, the signal processor **110** includes processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the detectors **106**. The signal processor **110** can be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **110** can provide various signals that control the operation of the sensor **101**. For example, the signal processor **110** can provide an emitter control signal to the driver **111**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **104**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **104** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front end interface **108** is used, the control signal from the signal processor **110** can provide synchronization with the ADC in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **113** can be included in the front-end interface **108** and/or in the signal processor **110**. This memory **113** can serve as a buffer or storage location for the front-end interface **108** and/or the signal processor **110**, among other uses.

The user interface **112** can provide an output, e.g., on a display, for presentation to a user of the data collection system **100**. The user interface **112** can be implemented as a touch-screen display, an LCD display, an organic LED display, or the like. In addition, the user interface **112** can be manipulated to allow for measurement on the non-dominant side of patient. For example, the user interface **112** can include a flip screen, a screen that can be moved from one side to another on the monitor **109**, or can include an ability to reorient its display indicia responsive to user input or device orientation. In alternative embodiments, the data collection system **100** can be provided without a user interface **112** and can simply provide an output signal to a separate display or system.

A storage device **114** and a network interface **116** represent other optional output connections that can be included in the monitor **109**. The storage device **114** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **114**, which can be executed by the signal processor **110** or another processor of the monitor **109**. The

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network interface **116** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **109** to communicate and share data with other devices. The monitor **109** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **112**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the data collection system **100** can include various other components or can be configured in different ways. For example, the sensor **101** can have both the emitter **104** and detectors **106** on the same side of the measurement site **102** and use reflectance to measure analytes. The data collection system **100** can also include a sensor that measures the power of light emitted from the emitter **104**.

FIGS. 2A through 2D illustrate example monitoring devices **200** in which the data collection system **100** can be housed. Advantageously, in certain embodiments, some or all of the example monitoring devices **200** shown can have a shape and size that allows a user to operate it with a single hand or attach it, for example, to a patient's body or limb. Although several examples are shown, many other monitoring device configurations can be used to house the data collection system **100**. In addition, certain of the features of the monitoring devices **200** shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices **200** shown.

Referring specifically to FIG. 2A, an example monitoring device **200A** is shown, in which a sensor **201a** and a monitor **209a** are integrated into a single unit. The monitoring device **200A** shown is a handheld or portable device that can measure glucose and other analytes in a patient's finger. The sensor **201a** includes an emitter shell **204a** and a detector shell **206a**. The depicted embodiment of the monitoring device **200A** also includes various control buttons **208a** and a display **210a**.

The sensor **201a** can be constructed of white material used for reflective purposes (such as white silicone or plastic), which can increase the usable signal at the detector **106** by forcing light back into the sensor **201a**. Pads in the emitter shell **204a** and the detector shell **206a** can contain separated windows to prevent or reduce mixing of light signals, for example, from distinct quadrants on a patient's finger. In addition, these pads can be made of a relatively soft material, such as a gel or foam, in order to conform to the shape, for example, of a patient's finger. The emitter shell **204a** and the detector shell **206a** can also include absorbing black or grey material portions to prevent or reduce ambient light from entering into the sensor **201a**.

In some embodiments, some or all portions of the emitter shell **204a** and/or detector shell **206a** can be detachable and/or disposable. For example, some or all portions of the shells **204a** and **206a** can be removable pieces. The removability of the shells **204a** and **206a** can be useful for sanitary purposes or for sizing the sensor **201a** to different patients. The monitor **209a** can include a fitting, slot, magnet, or other connecting mechanism to allow the sensor **201c** to be removably attached to the monitor **209a**.

The monitoring device **200a** also includes optional control buttons **208a** and a display **210a** that can allow the user to control the operation of the device. For example, a user can operate the control buttons **208a** to view one or more measurements of various analytes, such as glucose. In

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addition, the user can operate the control buttons **208a** to view other forms of information, such as graphs, histograms, measurement data, trend measurement data, parameter combination views, wellness indications, and the like. Many parameters, trends, alarms and parameter displays could be output to the display **210a**, such as those that are commercially available through a wide variety of noninvasive monitoring devices from Masimo® Corporation of Irvine, Calif.

Furthermore, the controls **208a** and/or display **210a** can provide functionality for the user to manipulate settings of the monitoring device **200a**, such as alarm settings, emitter settings, detector settings, and the like. The monitoring device **200a** can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button.

FIG. 2B illustrates another example of a monitoring device **200B**. In the depicted embodiment, the monitoring device **200B** includes a finger clip sensor **201b** connected to a monitor **209b** via a cable **212**. In the embodiment shown, the monitor **209b** includes a display **210b**, control buttons **208b** and a power button. Moreover, the monitor **209b** can advantageously include electronic processing, signal processing, and data storage devices capable of receiving signal data from said sensor **201b**, processing the signal data to determine one or more output measurement values indicative of one or more physiological parameters of a monitored patient, and displaying the measurement values, trends of the measurement values, combinations of measurement values, and the like.

The cable **212** connecting the sensor **201b** and the monitor **209b** can be implemented using one or more wires, optical fiber, flex circuits, or the like. In some embodiments, the cable **212** can employ twisted pairs of conductors in order to minimize or reduce cross-talk of data transmitted from the sensor **201b** to the monitor **209b**. Various lengths of the cable **212** can be employed to allow for separation between the sensor **201b** and the monitor **209b**. The cable **212** can be fitted with a connector (male or female) on either end of the cable **212** so that the sensor **201b** and the monitor **209b** can be connected and disconnected from each other. Alternatively, the sensor **201b** and the monitor **209b** can be coupled together via a wireless communication link, such as an infrared link, radio frequency channel, or any other wireless communication protocol and channel.

The monitor **209b** can be attached to the patient. For example, the monitor **209b** can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like. The monitor **209b** can also include a fitting, slot, magnet, LEMO snap-click connector, or other connecting mechanism to allow the cable **212** and sensor **201b** to be attached to the monitor **209b**.

The monitor **209b** can also include other components, such as a speaker, power button, removable storage or memory (e.g., a flash card slot), an AC power port, and one or more network interfaces, such as a universal serial bus interface or an Ethernet port. For example, the monitor **209b** can include a display **210b** that can indicate a measurement for glucose, for example, in mg/dL. Other analytes and forms of display can also appear on the monitor **209b**.

In addition, although a single sensor **201b** with a single monitor **209b** is shown, different combinations of sensors and device pairings can be implemented. For example, multiple sensors can be provided for a plurality of differing patient types or measurement sites or even patient fingers.

FIG. 2C illustrates yet another example of monitoring device **200C** that can house the data collection system **100**. Like the monitoring device **200B**, the monitoring device

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200C includes a finger clip sensor **201c** connected to a monitor **209c** via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. 2B. The monitor **209c** can include all of the features of the monitor **200B** described above. For example, the monitor **209c** includes buttons **208c** and a display **210c**. The monitor **209c** shown also includes straps **214c** that allow the monitor **209c** to be attached to a patient's limb or the like.

FIG. 2D illustrates yet another example of monitoring device **200D** that can house the data collection system **100**. Like the monitoring devices **200B** and **200C**, the monitoring device **200D** includes a finger clip sensor **201d** connected to a monitor **209d** via a cable **212**. The cable **212** can have all of the features described above with respect to FIG. 2B. In addition to having some or all of the features described above with respect to FIGS. 2B and 2C, the monitoring device **200D** includes an optional universal serial bus (USB) port **216** and an Ethernet port **218**. The USB port **216** and the Ethernet port **218** can be used, for example, to transfer information between the monitor **209d** and a computer (not shown) via a cable. Software stored on the computer can provide functionality for a user to, for example, view physiological data and trends, adjust settings and download firmware updates to the monitor **209b**, and perform a variety of other functions. The USB port **216** and the Ethernet port **218** can be included with the other monitoring devices **200A**, **200B**, and **200C** described above.

FIGS. 3A through 3C illustrate more detailed examples of embodiments of a sensor **301a**. The sensor **301a** shown can include all of the features of the sensors **100** and **200** described above.

Referring to FIG. 3A, the sensor **301a** in the depicted embodiment is a clothespin-shaped clip sensor that includes an enclosure **302a** for receiving a patient's finger. The enclosure **302a** is formed by an upper section or emitter shell **304a**, which is pivotably connected with a lower section or detector shell **306a**. The emitter shell **304a** can be biased with the detector shell **306a** to close together around a pivot point **303a** and thereby sandwich finger tissue between the emitter and detector shells **304a**, **306a**.

In an embodiment, the pivot point **303a** advantageously includes a pivot capable of adjusting the relationship between the emitter and detector shells **304a**, **306a** to effectively level the sections when applied to a tissue site. In another embodiment, the sensor **301a** includes some or all features of the finger clip described in U.S. Publication No. 2006/0211924, incorporated above, such as a spring that causes finger clip forces to be distributed along the finger. Paragraphs [0096] through [0105], which describe this feature, are hereby specifically incorporated by reference.

The emitter shell **304a** can position and house various emitter components of the sensor **301a**. It can be constructed of reflective material (e.g., white silicone or plastic) and/or can be metallic or include metalized plastic (e.g., including carbon and aluminum) to possibly serve as a heat sink. The emitter shell **304a** can also include absorbing opaque material, such as, for example, black or grey colored material, at various areas, such as on one or more flaps **307a**, to reduce ambient light entering the sensor **301a**.

The detector shell **306a** can position and house one or more detector portions of the sensor **301a**. The detector shell **306a** can be constructed of reflective material, such as white silicone or plastic. As noted, such materials can increase the usable signal at a detector by forcing light back into the tissue and measurement site (see FIG. 1). The detector shell

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306a can also include absorbing opaque material at various areas, such as lower area 308a, to reduce ambient light entering the sensor 301a.

Referring to FIGS. 3B and 3C, an example of finger bed 310 is shown in the sensor 301b. The finger bed 310 includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed 310 includes one or more ridges or channels 314. Each of the ridges 314 has a generally convex shape that can facilitate increasing traction or gripping of the patient's finger to the finger bed. Advantageously, the ridges 314 can improve the accuracy of spectroscopic analysis in certain embodiments by reducing noise that can result from a measurement site moving or shaking loose inside of the sensor 301a. The ridges 314 can be made from reflective or opaque materials in some embodiments to further increase SNR. In other implementations, other surface shapes can be used, such as, for example, generally flat, concave, or convex finger beds 310.

Finger bed 310 can also include an embodiment of a tissue thickness adjuster or protrusion 305. The protrusion 305 includes a measurement site contact area 370 (see FIG. 3C) that can contact body tissue of a measurement site. The protrusion 305 can be removed from or integrated with the finger bed 310. Interchangeable, different shaped protrusions 305 can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

Referring specifically to FIG. 3C, the contact area 370 of the protrusion 305 can include openings or windows 320, 321, 322, and 323. When light from a measurement site passes through the windows 320, 321, 322, and 323, the light can reach one or more photodetectors (see FIG. 3E). In an embodiment, the windows 320, 321, 322, and 323 mirror specific detector placements layouts such that light can impinge through the protrusion 305 onto the photodetectors. Any number of windows 320, 321, 322, and 323 can be employed in the protrusion 305 to allow light to pass from the measurement site to the photodetectors.

The windows 320, 321, 322, and 323 can also include shielding, such as an embedded grid of wiring or a conductive glass coating, to reduce noise from ambient light or other electromagnetic noise. The windows 320, 321, 322, and 323 can be made from materials, such as plastic or glass. In some embodiments, the windows 320, 321, 322, and 323 can be constructed from conductive glass, such as indium tin oxide (ITO) coated glass. Conductive glass can be useful because its shielding is transparent, and thus allows for a larger aperture versus a window with an embedded grid of wiring. In addition, in certain embodiments, the conductive glass does not need openings in its shielding (since it is transparent), which enhances its shielding performance. For example, some embodiments that employ the conductive glass can attain up to an about 40% to about 50% greater signal than non-conductive glass with a shielding grid. In addition, in some embodiments, conductive glass can be useful for shielding noise from a greater variety of directions than non-conductive glass with a shielding grid.

Turning to FIG. 3B, the sensor 301a can also include a shielding 315a, such as a metal cage, box, metal sheet, perforated metal sheet, a metal layer on a non-metal material, or the like. The shielding 315a is provided in the depicted embodiment below or embedded within the protrusion 305 to reduce noise. The shielding 315a can be constructed from a conductive material, such as copper. The shielding 315a can include one or more openings or windows (not shown). The windows can be made from glass or plastic to thereby allow light that has passed through the

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windows 320, 321, 322, and 323 on an external surface of the protrusion 305 (see FIG. 3C) to pass through to one or more photodetectors that can be enclosed or provided below (see FIG. 3E).

In some embodiments, the shielding cage for shielding 315a can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding cage can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces 108.

In an embodiment, the photodetectors can be positioned within or directly beneath the protrusion 305 (see FIG. 3E). In such cases, the mean optical path length from the emitters to the detectors can be reduced and the accuracy of blood analyte measurement can increase. For example, in one embodiment, a convex bump of about 1 mm to about 3 mm in height and about 10 mm² to about 60 mm² was found to help signal strength by about an order of magnitude versus other shapes. Of course other dimensions and sizes can be employed in other embodiments. Depending on the properties desired, the length, width, and height of the protrusion 305 can be selected. In making such determinations, consideration can be made of protrusion's 305 effect on blood flow at the measurement site and mean path length for optical radiation passing through openings 320, 321, 322, and 323. Patient comfort can also be considered in determining the size and shape of the protrusion.

In an embodiment, the protrusion 305 can include a pliant material, including soft plastic or rubber, which can somewhat conform to the shape of a measurement site. Pliant materials can improve patient comfort and tactility by conforming the measurement site contact area 370 to the measurement site. Additionally, pliant materials can minimize or reduce noise, such as ambient light. Alternatively, the protrusion 305 can be made from a rigid material, such as hard plastic or metal.

Rigid materials can improve measurement accuracy of a blood analyte by conforming the measurement site to the contact area 370. The contact area 370 can be an ideal shape for improving accuracy or reducing noise. Selecting a material for the protrusion 305 can include consideration of materials that do not significantly alter blood flow at the measurement site. The protrusion 305 and the contact area 370 can include a combination of materials with various characteristics.

The contact area 370 serves as a contact surface for the measurement site. For example, in some embodiments, the contact area 370 can be shaped for contact with a patient's finger. Accordingly, the contact area 370 can be sized and shaped for different sizes of fingers. The contact area 370 can be constructed of different materials for reflective purposes as well as for the comfort of the patient. For example, the contact area 370 can be constructed from materials having various hardness and textures, such as plastic, gel, foam, and the like.

The formulas and analysis that follow with respect to FIG. 5 provide insight into how selecting these variables can alter transmittance and intensity gain of optical radiation that has been applied to the measurement site. These examples do not limit the scope of this disclosure.

Referring to FIG. 5, a plot 500 is shown that illustrates examples of effects of embodiments of the protrusion 305 on the SNR at various wavelengths of light. As described above, the protrusion 305 can assist in conforming the tissue

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and effectively reduce its mean path length. In some instances, this effect by the protrusion **305** can have significant impact on increasing the SNR.

According to the Beer Lambert law, a transmittance of light (I) can be expressed as follows: $I = I_0 * e^{-m * b * c}$, where I_0 is the initial power of light being transmitted, m is the path length traveled by the light, and the component “ $b * c$ ” corresponds to the bulk absorption of the light at a specific wavelength of light. For light at about 1600 nm to about 1700 nm, for example, the bulk absorption component is generally around 0.7 mm^{-1} . Assuming a typical finger thickness of about 12 mm and a mean path length of 20 mm due to tissue scattering, then $I = I_0 * e^{(-20 * 0.7)}$.

In an embodiment where the protrusion **305** is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm (see box **510**). This results in a new transmittance, $I_1 = I_0 * e^{(-16.6 * 0.7)}$. A curve for a typical finger (having a mean path length of 20 mm) across various wavelengths is shown in the plot **500** of FIG. **5**. The plot **500** illustrates potential effects of the protrusion **305** on the transmittance. As illustrated, comparing I and I_1 results in an intensity gain of $e^{(-16.6 * 0.7)} / e^{(-20 * 0.7)}$, which is about a 10 times increase for light in the about 1600 nm to about 1700 nm range. Such an increase can affect the SNR at which the sensor can operate. The foregoing gains can be due at least in part to the about 1600 nm to about 1700 nm range having high values in bulk absorptions (water, protein, and the like), e.g., about 0.7 mm^{-1} . The plot **500** also shows improvements in the visible/near-infrared range (about 600 nm to about 1300 nm).

Turning again to FIGS. **3A** through **3C**, an example heat sink **350a** is also shown. The heat sink **350a** can be attached to, or protrude from an outer surface of, the sensor **301a**, thereby providing increased ability for various sensor components to dissipate excess heat. By being on the outer surface of the sensor **301a** in certain embodiments, the heat sink **350a** can be exposed to the air and thereby facilitate more efficient cooling. In an embodiment, one or more of the emitters (see FIG. **1**) generate sufficient heat that inclusion of the heat sink **350a** can advantageously allow the sensor **301a** to remain safely cooled. The heat sink **350a** can include one or more materials that help dissipate heat, such as, for example, aluminum, steel, copper, carbon, combinations of the same, or the like. For example, in some embodiments, the emitter shell **304a** can include a heat conducting material that is also readily and relatively inexpensively moldable into desired shapes and forms.

In some embodiments, the heat sink **350a** includes metalized plastic. The metalized plastic can include aluminum and carbon, for example. The material can allow for improved thermal conductivity and diffusivity, which can increase commercial viability of the heat sink. In some embodiments, the material selected to construct the heat sink **350a** can include a thermally conductive liquid crystalline polymer, such as CoolPoly® D5506, commercially available from Cool Polymers®, Inc. of Warwick, R.I. Such a material can be selected for its electrically non-conductive and dielectric properties so as, for example, to aid in electrical shielding. In an embodiment, the heat sink **350a** provides improved heat transfer properties when the sensor **301a** is active for short intervals of less than a full day's use. In an embodiment, the heat sink **350a** can advantageously provide improved heat transfers in about three (3) to about four (4) minute intervals, for example, although a heat sink **350a** can be selected that performs effectively in shorter or longer intervals.

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Moreover, the heat sink **350a** can have different shapes and configurations for aesthetic as well as for functional purposes. In an embodiment, the heat sink is configured to maximize heat dissipation, for example, by maximizing surface area. In an embodiment, the heat sink **350a** is molded into a generally curved surface and includes one or more fins, undulations, grooves, or channels. The example heat sink **350a** shown includes fins **351a** (see FIG. **3A**).

An alternative shape of a sensor **301b** and heat sink **350b** is shown in FIG. **3D**. The sensor **301b** can include some or all of the features of the sensor **301a**. For example, the sensor **301b** includes an enclosure **302b** formed by an emitter shell **304b** and a detector shell **306b**, pivotably connected about a pivot **303a**. The emitter shell **304b** can also include absorbing opaque material on one or more flaps **307b**, and the detector shell **306a** can also include absorbing opaque material at various areas, such as lower area **308b**.

However, the shape of the sensor **301b** is different in this embodiment. In particular, the heat sink **350b** includes comb protrusions **351b**. The comb protrusions **351b** are exposed to the air in a similar manner to the fins **351a** of the heat sink **350a**, thereby facilitating efficient cooling of the sensor **301b**.

FIG. **3E** illustrates a more detailed example of a detector shell **306b** of the sensor **301b**. The features described with respect to the detector shell **306b** can also be used with the detector shell **306a** of the sensor **301a**.

As shown, the detector shell **306b** includes detectors **316**. The detectors **316** can have a predetermined spacing **340** from each other, or a spatial relationship among one another that results in a spatial configuration. This spatial configuration can purposefully create a variation of path lengths among detectors **316** and the emitter discussed above.

In the depicted embodiment, the detector shell **316** can hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays can also be useful to detect light piping (e.g., light that bypasses measurement site **102**). In the detector shell **316**, walls can be provided to separate the individual photodiode arrays to prevent or reduce mixing of light signals from distinct quadrants. In addition, the detector shell **316** can be covered by windows of transparent material, such as glass, plastic, or the like, to allow maximum or increased transmission of power light captured. In various embodiments, the transparent materials used can also be partially transparent or translucent or can otherwise pass some or all of the optical radiation passing through them. As noted, this window can include some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

As further illustrated by FIG. **3E**, the detectors **316** can have a spatial configuration of a grid. However, the detectors **316** can be arranged in other configurations that vary the path length. For example, the detectors **316** can be arranged in a linear array, a logarithmic array, a two-dimensional array, a zig-zag pattern, or the like. Furthermore, any number of the detectors **316** can be employed in certain embodiments.

FIG. **3F** illustrates another embodiment of a sensor **301f**. The sensor **301f** can include some or all of the features of the sensor **301a** of FIG. **3A** described above. For example, the sensor **301f** includes an enclosure **302f** formed by an upper section or emitter shell **304f**, which is pivotably connected with a lower section or detector shell **306f** around a pivot point **303f**. The emitter shell **304f** can also include absorbing opaque material on various areas, such as on one or more flaps **307f**, to reduce ambient light entering the sensor **301f**.

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The detector shell **306f** can also include absorbing opaque material at various areas, such as a lower area **308f**. The sensor **301f** also includes a heat sink **350f**, which includes fins **351f**.

In addition to these features, the sensor **301f** includes a flex circuit cover **360**, which can be made of plastic or another suitable material. The flex circuit cover **360** can cover and thereby protect a flex circuit (not shown) that extends from the emitter shell **304f** to the detector shell **306f**. An example of such a flex circuit is illustrated in U.S. Publication No. 2006/0211924, incorporated above (see FIG. **46** and associated description, which is hereby specifically incorporated by reference). The flex circuit cover **360** is shown in more detail below in FIG. **17**.

In addition, sensors **301a-f** has extra length—extends to second joint on finger—Easier to place, harder to move due to cable, better for light piping.

FIGS. **4A** through **4C** illustrate example arrangements of a protrusion **405**, which is an embodiment of the protrusion **305** described above. In an embodiment, the protrusion **405** can include a measurement site contact area **470**. The measurement site contact area **470** can include a surface that molds body tissue of a measurement site, such as a finger, into a flat or relatively flat surface.

The protrusion **405** can have dimensions that are suitable for a measurement site such as a patient's finger. As shown, the protrusion **405** can have a length **400**, a width **410**, and a height **430**. The length **400** can be from about 9 to about 11 millimeters, e.g., about 10 millimeters. The width **410** can be from about 7 to about 9 millimeters, e.g., about 8 millimeters. The height **430** can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions **400**, **410**, and **430** can be selected such that the measurement site contact area **470** includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.

The measurement site contact area **470** can also include differently shaped surfaces that conform the measurement site into different shapes. For example, the measurement site contact area **470** can be generally curved and/or convex with respect to the measurement site. The measurement site contact area **470** can be other shapes that reduce or even minimize air between the protrusion **405** and/or the measurement site. Additionally, the surface pattern of the measurement site contact area **470** can vary from smooth to bumpy, e.g., to provide varying levels of grip.

In FIGS. **4A** and **4C**, openings or windows **420**, **421**, **422**, and **423** can include a wide variety of shapes and sizes, including for example, generally square, circular, triangular, or combinations thereof. The windows **420**, **421**, **422**, and **423** can be of non-uniform shapes and sizes. As shown, the windows **420**, **421**, **422**, and **423** can be evenly spaced out in a grid like arrangement. Other arrangements or patterns of arranging the windows **420**, **421**, **422**, and **423** are possible. For example, the windows **420**, **421**, **422**, and **423** can be placed in a triangular, circular, or linear arrangement. In some embodiments, the windows **420**, **421**, **422**, and **423** can be placed at different heights with respect to the finger bed **310** of FIG. **3**. The windows **420**, **421**, **422**, and **423** can also mimic or approximately mimic a configuration of, or even house, a plurality of detectors.

FIGS. **6A** through **6D** illustrate another embodiment of a protrusion **605** that can be used as the tissue shaper **105** described above or in place of the protrusions **305**, **405** described above. The depicted protrusion **605** is a partially

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cylindrical lens having a partial cylinder **608** and an extension **610**. The partial cylinder **608** can be a half cylinder in some embodiments; however, a smaller or greater portion than half of a cylinder can be used. Advantageously, in certain embodiments, the partially cylindrical protrusion **605** focuses light onto a smaller area, such that fewer detectors can be used to detect the light attenuated by a measurement site.

FIG. **6A** illustrates a perspective view of the partially cylindrical protrusion **605**. FIG. **6B** illustrates a front elevation view of the partially cylindrical protrusion **605**. FIG. **6C** illustrates a side view of the partially cylindrical protrusion **605**. FIG. **6D** illustrates a top view of the partially cylindrical protrusion **605**.

Advantageously, in certain embodiments, placing the partially cylindrical protrusion **605** over the photodiodes in any of the sensors described above adds multiple benefits to any of the sensors described above. In one embodiment, the partially cylindrical protrusion **605** penetrates into the tissue and reduces the path length of the light traveling in the tissue, similar to the protrusions described above.

The partially cylindrical protrusion **605** can also collect light from a large surface and focus down the light to a smaller area. As a result, in certain embodiments, signal strength per area of the photodiode can be increased. The partially cylindrical protrusion **605** can therefore facilitate a lower cost sensor because, in certain embodiments, less photodiode area can be used to obtain the same signal strength. Less photodiode area can be realized by using smaller photodiodes or fewer photodiodes (see, e.g., FIG. **14**). If fewer or smaller photodiodes are used, the partially cylindrical protrusion **605** can also facilitate an improved SNR of the sensor because fewer or smaller photodiodes can have less dark current.

The dimensions of the partially cylindrical protrusion **605** can vary based on, for instance, a number of photodiodes used with the sensor. Referring to FIG. **6C**, the overall height of the partially cylindrical protrusion **605** (measurement "a") in some implementations is about 1 to about 3 mm. A height in this range can allow the partially cylindrical protrusion **605** to penetrate into the pad of the finger or other tissue and reduce the distance that light travels through the tissue. Other heights, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the chosen height of the partially cylindrical protrusion **605** can be selected based on the size of the measurement site, whether the patient is an adult or child, and so on. In an embodiment, the height of the protrusion **605** is chosen to provide as much tissue thickness reduction as possible while reducing or preventing occlusion of blood vessels in the tissue.

Referring to FIG. **6D**, the width of the partially cylindrical protrusion **605** (measurement "b") can be about 3 to about 5 mm. In one embodiment, the width is about 4 mm. In one embodiment, a width in this range provides good penetration of the partially cylindrical protrusion **605** into the tissue to reduce the path length of the light. Other widths, however, of the partially cylindrical protrusion **605** can also accomplish this objective. For example, the width of the partially cylindrical protrusion **605** can vary based on the size of the measurement site, whether the patient is an adult or child, and so on. In addition, the length of the protrusion **605** could be about 10 mm, or about 8 mm to about 12 mm, or smaller than 8 mm or greater than 12 mm.

In certain embodiments, the focal length (f) for the partially cylindrical protrusion **605** can be expressed as:

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$$f = \frac{R}{n-1},$$

where R is the radius of curvature of the partial cylinder **608** and n is the index of refraction of the material used. In certain embodiments, the radius of curvature can be between about 1.5 mm and about 2 mm. In another embodiment, the partially cylindrical protrusion **605** can include a material, such as nBK7 glass, with an index of refraction of around 1.5 at 1300 nm, which can provide focal lengths of between about 3 mm and about 4 mm.

A partially cylindrical protrusion **605** having a material with a higher index of refraction such as nSF11 glass (e.g., n=1.75 at 1300 nm) can provide a shorter focal length and possibly a smaller photodiode chip, but can also cause higher reflections due to the index of refraction mismatch with air. Many types of glass or plastic can be used with index of refraction values ranging from, for example, about 1.4 to about 1.9. The index of refraction of the material of the protrusion **605** can be chosen to improve or optimize the light focusing properties of the protrusion **605**. A plastic partially cylindrical protrusion **605** could provide the cheapest option in high volumes but can also have some undesired light absorption peaks at wavelengths higher than 1500 nm. Other focal lengths and materials having different indices of refraction can be used for the partially cylindrical protrusion **605**.

Placing a photodiode at a given distance below the partially cylindrical protrusion **605** can facilitate capturing some or all of the light traveling perpendicular to the lens within the active area of the photodiode (see FIG. 14). Different sizes of the partially cylindrical protrusion **605** can use different sizes of photodiodes. The extension **610** added onto the bottom of the partial cylinder **608** is used in certain embodiments to increase the height of the partially cylindrical protrusion **605**. In an embodiment, the added height is such that the photodiodes are at or are approximately at the focal length of the partially cylindrical protrusion **605**. In an embodiment, the added height provides for greater thinning of the measurement site. In an embodiment, the added height assists in deflecting light piped through the sensor. This is because light piped around the sensor passes through the side walls of the added height without being directed toward the detectors. The extension **610** can also further facilitate the protrusion **605** increasing or maximizing the amount of light that is provided to the detectors. In some embodiments, the extension **610** can be omitted.

FIG. 6E illustrates another view of the sensor **301f** of FIG. 3F, which includes an embodiment of a partially cylindrical protrusion **605b**. Like the sensor **301A** shown in FIGS. 3B and 3C, the sensor **301f** includes a finger bed **310f**. The finger bed **310f** includes a generally curved surface shaped generally to receive tissue, such as a human digit. The finger bed **310f** also includes the ridges or channels **314** described above with respect to FIGS. 3B and 3C.

The example of finger bed **310f** shown also includes the protrusion **605b**, which includes the features of the protrusion **605** described above. In addition, the protrusion **605b** also includes chamfered edges **607** on each end to provide a more comfortable surface for a finger to slide across (see also FIG. 14D). In another embodiment, the protrusion **605b** could instead include a single chamfered edge **607** proximal to the ridges **314**. In another embodiment, one or both of the chamfered edges **607** could be rounded.

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The protrusion **605b** also includes a measurement site contact area **670** that can contact body tissue of a measurement site. The protrusion **605b** can be removed from or integrated with the finger bed **310f**. Interchangeable, differently shaped protrusions **605b** can also be provided, which can correspond to different finger shapes, characteristics, opacity, sizes, or the like.

FIGS. 7A and 7B illustrate block diagrams of sensors **701** that include example arrangements of conductive glass or conductive coated glass for shielding. Advantageously, in certain embodiments, the shielding can provide increased SNR. The features of the sensors **701** can be implemented with any of the sensors **101**, **201**, **301** described above. Although not shown, the partially cylindrical protrusion **605** of FIG. 6 can also be used with the sensors **701** in certain embodiments.

For example, referring specifically to FIG. 7A, the sensor **701a** includes an emitter housing **704a** and a detector housing **706**. The emitter housing **704a** includes LEDs **104**. The detector housing **706a** includes a tissue bed **710a** with an opening or window **703a**, the conductive glass **730a**, and one or more photodiodes for detectors **106** provided on a submount **707a**.

During operation, a finger **102** can be placed on the tissue bed **710a** and optical radiation can be emitted from the LEDs **104**. Light can then be attenuated as it passes through or is reflected from the tissue of the finger **102**. The attenuated light can then pass through the opening **703a** in the tissue bed **710a**. Based on the received light, the detectors **106** can provide a detector signal **107**, for example, to the front end interface **108** (see FIG. 1).

In the depicted embodiment, the conductive glass **730** is provided in the opening **703**. The conductive glass **730** can thus not only permit light from the finger to pass to the detectors **106**, but it can also supplement the shielding of the detectors **106** from noise. The conductive glass **730** can include a stack or set of layers. In FIG. 7A, the conductive glass **730a** is shown having a glass layer **731** proximate the finger **102** and a conductive layer **733** electrically coupled to the shielding **790a**.

In an embodiment, the conductive glass **730a** can be coated with a conductive, transparent or partially transparent material, such as a thin film of indium tin oxide (ITO). To supplement electrical shielding effects of a shielding enclosure **790a**, the conductive glass **730a** can be electrically coupled to the shielding enclosure **790a**. The conductive glass **730a** can be electrically coupled to the shielding **704a** based on direct contact or via other connection devices, such as a wire or another component.

The shielding enclosure **790a** can be provided to encompass the detectors **106** to reduce or prevent noise. For example, the shielding enclosure **790a** can be constructed from a conductive material, such as copper, in the form of a metal cage. The shielding or enclosure **a** can include an opaque material to not only reduce electrical noise, but also ambient optical noise.

In some embodiments, the shielding enclosure **790a** can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790a** can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

Referring to FIG. 7B, another block diagram of an example sensor **701b** is shown. A tissue bed **710b** of the

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sensor **701b** includes a protrusion **705b**, which is in the form of a convex bump. The protrusion **705b** can include all of the features of the protrusions or tissue shaping materials described above. For example, the protrusion **705b** includes a contact area **370** that comes in contact with the finger **102** and which can include one or more openings **703b**. One or more components of conductive glass **730b** can be provided in the openings **703**. For example, in an embodiment, each of the openings **703** can include a separate window of the conductive glass **730b**. In an embodiment, a single piece of the conductive glass **730b** can be used for some or all of the openings **703b**. The conductive glass **730b** is smaller than the conductive glass **730a** in this particular embodiment.

A shielding enclosure **790b** is also provided, which can have all the features of the shielding enclosure **790a**. The shielding enclosure **790b** is smaller than the shielding enclosure **790a**; however, a variety of sizes can be selected for the shielding enclosures **790**.

In some embodiments, the shielding enclosure **790b** can be constructed in a single manufactured component with or without the use of conductive glass. This form of construction may be useful in order to reduce costs of manufacture as well as assist in quality control of the components. Furthermore, the shielding enclosure **790b** can also be used to house various other components, such as sigma delta components for various embodiments of front end interfaces **108**.

FIGS. **8A** through **8D** illustrate a perspective view, side views, and a bottom elevation view of the conductive glass described above with respect to the sensors **701a**, **701b**. As shown in the perspective view of FIG. **8A** and side view of FIG. **8B**, the conductive glass **730** includes the electrically conductive material **733** described above as a coating on the glass layer **731** described above to form a stack. In an embodiment where the electrically conductive material **733** includes indium tin oxide, surface resistivity of the electrically conductive material **733** can range approximately from 30 ohms per square inch to 500 ohms per square inch, or approximately 30, 200, or 500 ohms per square inch. As would be understood by a person of skill in the art from the present disclosure, other resistivities can also be used which are less than 30 ohms or more than 500 ohms. Other transparent, electrically conductive materials can be used as the material **733**.

Although the conductive material **733** is shown spread over the surface of the glass layer **731**, the conductive material **733** can be patterned or provided on selected portions of the glass layer **731**. Furthermore, the conductive material **733** can have uniform or varying thickness depending on a desired transmission of light, a desired shielding effect, and other considerations.

In FIG. **8C**, a side view of a conductive glass **830a** is shown to illustrate an embodiment where the electrically conductive material **733** is provided as an internal layer between two glass layers **731**, **835**. Various combinations of integrating electrically conductive material **733** with glass are possible. For example, the electrically conductive material **733** can be a layer within a stack of layers. This stack of layers can include one or more layers of glass **731**, **835**, as well as one or more layers of conductive material **733**. The stack can include other layers of materials to achieve desired characteristics.

In FIG. **8D**, a bottom perspective view is shown to illustrate an embodiment where a conductive glass **830b** can include conductive material **837** that occupies or covers a portion of a glass layer **839**. This embodiment can be useful, for example, to create individual, shielded windows for

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detectors **106**, such as those shown in FIG. **3C**. The conductive material **837** can be patterned to include an area **838** to allow light to pass to detectors **106** and one or more strips **841** to couple to the shielding **704** of FIG. **7**.

Other configurations and patterns for the conductive material can be used in certain embodiments, such as, for example, a conductive coating lining periphery edges, a conductive coating outlaid in a pattern including a grid or other pattern, a speckled conductive coating, coating outlaid in lines in either direction or diagonally, varied thicknesses from the center out or from the periphery in, or other suitable patterns or coatings that balance the shielding properties with transparency considerations.

FIG. **9** depicts an example graph **900** that illustrates comparative results obtained by an example sensor having components similar to those disclosed above with respect to FIGS. **7** and **8**. The graph **900** depicts the results of the percentage of transmission of varying wavelengths of light for different types of windows used in the sensors described above.

A line **915** on the graph **900** illustrates example light transmission of a window made from plain glass. As shown, the light transmission percentage of varying wavelengths of light is approximately 90% for a window made from plain glass. A line **920** on the graph **900** demonstrates an example light transmission percentage for an embodiment in which a window is made from glass having an ITO coating with a surface resistivity of 500 ohms per square inch. A line **925** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 200 ohms per square inch. A line **930** on the graph **900** shows an example light transmission for an embodiment in which a window is made from glass that includes a coating of ITO oxide with a surface resistivity of 30 ohms per square inch.

The light transmission percentage for a window with currently available embedded wiring can have a light transmission percentage of approximately 70%. This lower percentage of light transmission can be due to the opacity of the wiring employed in a currently available window with wiring. Accordingly, certain embodiments of glass coatings described herein can employ, for example, ITO coatings with different surface resistivity depending on the desired light transmission, wavelengths of light used for measurement, desired shielding effect, and other criteria.

FIGS. **10A** through **10B** illustrate comparative noise floors of example implementations of the sensors described above. Noise can include optical noise from ambient light and electro-magnetic noise, for example, from surrounding electrical equipment. In FIG. **10A**, a graph **1000** depicts possible noise floors for different frequencies of noise for an embodiment in which one of the sensors described above included separate windows for four (4) detectors **106**. One or more of the windows included an embedded grid of wiring as a noise shield. Symbols **1030-1033** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance can vary for each of the openings and based on the frequency of the noise.

In FIG. **10B**, a graph **1050** depicts a noise floor for frequencies of noise **1070** for an embodiment in which the sensor included separate openings for four (4) detectors **106** and one or more windows that include an ITO coating. In this embodiment, a surface resistivity of the ITO used was about 500 ohms per square inch. Symbols **1080-1083** illustrate the noise floor performance for this embodiment. As can be seen, the noise floor performance for this embodi-

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ment can vary less for each of the openings and provide lower noise floors in comparison to the embodiment of FIG. 10A.

FIG. 11A illustrates an example structure for configuring the set of optical sources of the emitters described above. As shown, an emitter 104 can include a driver 1105, a thermistor 1120, a set of top-emitting LEDs 1102 for emitting red and/or infrared light, a set of side-emitting LEDs 1104 for emitting near infrared light, and a submount 1106.

The thermistor 1120 can be provided to compensate for temperature variations. For example, the thermistor 1120 can be provided to allow for wavelength centroid and power drift of LEDs 1102 and 1104 due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. The temperature can be displayed on a display device and used by a caregiver. Such a temperature can also be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose. In addition, using a thermistor or other type of temperature sensitive device may be useful for detecting extreme temperatures at the measurement site that are too hot or too cold. The presence of low perfusion may also be detected, for example, when the finger of a patient has become too cold. Moreover, shifts in temperature at the measurement site can alter the absorption spectrum of water and other tissue in the measurement site. A thermistor's temperature reading can be used to adjust for the variations in absorption spectrum changes in the measurement site.

The driver 1105 can provide pulses of current to the emitter 1104. In an embodiment, the driver 1105 drives the emitter 1104 in a progressive fashion, for example, in an alternating manner based on a control signal from, for example, a processor (e.g., the processor 110). For example, the driver 1105 can drive the emitter 1104 with a series of pulses to about 1 milliwatt (mW) for visible light to light at about 1300 nm and from about 40 mW to about 100 mW for light at about 1600 nm to about 1700 nm. However, a wide number of driving powers and driving methodologies can be used. The driver 1105 can be synchronized with other parts of the sensor and can minimize or reduce any jitter in the timing of pulses of optical radiation emitted from the emitter 1104. In some embodiments, the driver 1105 is capable of driving the emitter 1104 to emit an optical radiation in a pattern that varies by less than about 10 parts-per-million; however other amounts of variation can be used.

The submount 1106 provides a support structure in certain embodiments for aligning the top-emitting LEDs 1102 and the side-emitting LEDs 1104 so that their optical radiation is transmitted generally towards the measurement site. In some embodiments, the submount 1106 is also constructed of aluminum nitride (AlN) or beryllium oxide (BEO) for heat dissipation, although other materials or combinations of materials suitable for the submount 1106 can be used.

FIG. 11B illustrates a configuration of emitting optical radiation into a measurement site for measuring a blood constituent or analyte like glucose. In some embodiments, emitter 104 may be driven in a progressive fashion to minimize noise and increase SNR of sensor 101. For example, emitter 104 may be driven based on a progression of power/current delivered to LEDs 1102 and 1104.

In some embodiments, emitter 104 may be configured to emit pulses centered about 905 nm, about 1050 nm, about 1200 nm, about 1300 nm, about 1330 nm, about 1610 nm, about 1640 nm, and about 1665 nm. In another embodiment, the emitter 104 may emit optical radiation ranging from

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about 860 nm to about 950 nm, about 950 nm to about 1100 nm, about 1100 nm to about 1270 nm, about 1250 nm to about 1350 nm, about 1300 nm to about 1360 nm, and about 1590 nm to about 1700 nm. Of course, emitter 104 may be configured to transmit any of a variety of wavelengths of visible, or near-infrared optical radiation.

For purposes of illustration, FIG. 11B shows a sequence of pulses of light at wavelengths of around 905 nm, around 1200 nm, around 1300 nm, and around 1330 nm from top emitting LEDs 1102. FIG. 11B also shows that emitter 104 may then emit pulses centered at around 1630 nm, around 1660 nm, and around 1615 nm from side emitting LEDs 1104. Emitter 104 may be progressively driven at higher power/current. This progression may allow driver circuit 1105 to stabilize in its operations, and thus, provide a more stable current/power to LEDs 1102 and 1104.

For example, as shown in FIG. 11B, the sequence of optical radiation pulses are shown having a logarithmic-like progression in power/current. In some embodiments, the timing of these pulses is based on a cycle of about 400 slots running at 48 kHz (e.g. each time slot may be approximately 0.02 ms or 20 microseconds). An artisan will recognize that term "slots" includes its ordinary meaning, which includes a time period that may also be expressed in terms of a frequency. In the example shown, pulses from top emitting LEDs 1102 may have a pulse width of about 40 time slots (e.g., about 0.8 ms) and an off period of about 4 time slots in between. In addition, pulses from side emitting LEDs 1104 (e.g., or a laser diode) may have a pulse width of about 60 time slots (e.g., about 1.25 ms) and a similar off period of about 4 time slots. A pause of about 70 time slots (e.g. 1.5 ms) may also be provided in order to allow driver circuit 1105 to stabilize after operating at higher current/power.

As shown in FIG. 11B, top emitting LEDs 1102 may be initially driven with a power to approximately 1 mW at a current of about 20-100 mA. Power in these LEDs may also be modulated by using a filter or covering of black dye to reduce power output of LEDs. In this example, top emitting LEDs 1102 may be driven at approximately 0.02 to 0.08 mW. The sequence of the wavelengths may be based on the current requirements of top emitting LEDs 502 for that particular wavelength. Of course, in other embodiments, different wavelengths and sequences of wavelengths may be output from emitter 104.

Subsequently, side emitting LEDs 1104 may be driven at higher powers, such as about 40-100 mW and higher currents of about 600-800 mA. This higher power may be employed in order to compensate for the higher opacity of tissue and water in measurement site 102 to these wavelengths. For example, as shown, pulses at about 1630 nm, about 1660 nm, and about 1615 nm may be output with progressively higher power, such as at about 40 mW, about 50 mW, and about 60 mW, respectively. In this embodiment, the order of wavelengths may be based on the optical characteristics of that wavelength in tissue as well as the current needed to drive side emitting LEDs 1104. For example, in this embodiment, the optical pulse at about 1615 nm is driven at the highest power due to its sensitivity in detecting analytes like glucose and the ability of light at this wavelength to penetrate tissue. Of course, different wavelengths and sequences of wavelengths may be output from emitter 104.

As noted, this progression may be useful in some embodiments because it allows the circuitry of driver circuit 1105 to stabilize its power delivery to LEDs 1102 and 1104. Driver circuit 1105 may be allowed to stabilize based on the duty cycle of the pulses or, for example, by configuring a

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variable waiting period to allow for stabilization of driver circuit **1105**. Of course, other variations in power/current and wavelength may also be employed in the present disclosure.

Modulation in the duty cycle of the individual pulses may also be useful because duty cycle can affect the signal noise ratio of the system **100**. That is, as the duty cycle is increased so may the signal to noise ratio.

Furthermore, as noted above, driver circuit **1105** may monitor temperatures of the LEDs **1102** and **1104** using the thermistor **1120** and adjust the output of LEDs **1102** and **1104** accordingly. Such a temperature may be to help sensor **101** correct for wavelength drift due to changes in water absorption, which can be temperature dependent.

FIG. **11C** illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. As shown, the emitter **104** can include components mounted on a substrate **1108** and on submount **1106**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**. Side emitting LEDs **1104** may be mounted on submount **1106**. As noted, side-emitting LEDs **1104** may be included in emitter **104** for emitting near infrared light.

As also shown, the sensor of FIG. **11C** may include a thermistor **1120**. As noted, the thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** and **1104** due to heating. In addition, other thermistors (not shown) can be employed, for example, to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In some embodiments, the emitter **104** may be implemented without the use of side emitting LEDs. For example, certain blood constituents, such as total hemoglobin, can be measured by embodiments of the disclosure without the use of side emitting LEDs. FIG. **11D** illustrates another exemplary emitter that may be employed in the sensor according to an embodiment of the disclosure. In particular, an emitter **104** that is configured for a blood constituent, such as total hemoglobin, is shown. The emitter **104** can include components mounted on a substrate **1108**. In particular, top-emitting LEDs **1102** for emitting red and/or infrared light may be mounted on substrate **1108**.

As also shown, the emitter of FIG. **11D** may include a thermistor **1120**. The thermistor **1120** can be provided to compensate for temperature variations. The thermistor **1120** can be provided to allow for wavelength centroid and power drift of LEDs **1102** due to heating.

FIG. **12A** illustrates a detector submount **1200** having photodiode detectors that are arranged in a grid pattern on the detector submount **1200** to capture light at different quadrants from a measurement site. One detector submount **1200** can be placed under each window of the sensors described above, or multiple windows can be placed over a single detector submount **1200**. The detector submount **1200** can also be used with the partially cylindrical protrusion **605** described above with respect to FIG. **6**.

The detectors include photodiode detectors 1-4 that are arranged in a grid pattern on the submount **1200** to capture light at different quadrants from the measurement site. As noted, other patterns of photodiodes, such as a linear row, or logarithmic row, can also be employed in certain embodiments.

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As shown, the detectors 1-4 may have a predetermined spacing from each other, or spatial relationship among one another that result in a spatial configuration. This spatial configuration can be configured to purposefully create a variation of path lengths among detectors **106** and the point light source discussed above.

Detectors may hold multiple (e.g., two, three, four, etc.) photodiode arrays that are arranged in a two-dimensional grid pattern. Multiple photodiode arrays may also be useful to detect light piping (i.e., light that bypasses measurement site **102**). As shown, walls may separate the individual photodiode arrays to prevent mixing of light signals from distinct quadrants. In addition, as noted, the detectors may be covered by windows of transparent material, such as glass, plastic, etc., to allow maximum transmission of power light captured. As noted, this window may comprise some shielding in the form of an embedded grid of wiring, or a conductive layer or coating.

FIGS. **12B** through **12D** illustrate a simplified view of exemplary arrangements and spatial configurations of photodiodes for detectors **106**. As shown, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a grid pattern on detector submount **1200** to capture light at different quadrants from measurement site **102**.

As noted, other patterns of photodiodes may also be employed in embodiments of the present disclosure, including, for example, stacked or other configurations recognizable to an artisan from the disclosure herein. For example, detectors **106** may be arranged in a linear array, a logarithmic array, a two-dimensional array, and the like. Furthermore, an artisan will recognize from the disclosure herein that any number of detectors **106** may be employed by embodiments of the present disclosure.

For example, as shown in FIG. **12B**, detectors **106** may comprise photodiode detectors 1-4 that are arranged in a substantially linear configuration on submount **1200**. In this embodiment shown, photodiode detectors 1-4 are substantially equally spaced apart (e.g., where the distance D is substantially the same between detectors 1-4).

In FIG. **12C**, photodiode detectors 1-4 may be arranged in a substantially linear configuration on submount **1200**, but may employ a substantially progressive, substantially logarithmic, or substantially semi-logarithmic spacing (e.g., where distances $D1 > D2 > D3$). This arrangement or pattern may be useful for use on a patient's finger and where the thickness of the finger gradually increases.

In FIG. **12D**, a different substantially grid pattern on submount **1200** of photodiode detectors 1-4 is shown. As noted, other patterns of detectors may also be employed in embodiments of the present invention.

FIGS. **12E** through **12H** illustrate several embodiments of photodiodes that may be used in detectors **106**. As shown in these figures, a photodiode **1202** of detector **106** may comprise a plurality of active areas **1204**. These active areas **204** may be coupled together via a common cathode **1206** or anode **1208** in order to provide a larger effective detection area.

In particular, as shown in FIG. **12E**, photodiode **1202** may comprise two (2) active areas **1204a** and **1204b**. In FIG. **12F**, photodiode **1202** may comprise four (4) active areas **1204c-f**. In FIG. **12G**, photodiode **1202** may comprise three (3) active areas **1204g-i**. In FIG. **12H**, photodiode **1202** may comprise nine (9) active areas **1204j-r**. The use of smaller active areas may be useful because smaller active areas can be easier to fabricate and can be fabricated with higher

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purity. However, one skilled in the art will recognize that various sizes of active areas may be employed in the photodiode 1202.

FIG. 13 illustrates an example multi-stream process 1300. The multi-stream process 1300 can be implemented by the data collection system 100 and/or by any of the sensors described above. As shown, a control signal from a signal processor 1310 controls a driver 1305. In response, an emitter 1304 generates a pulse sequence 1303 from its emitter (e.g., its LEDs) into a measurement site or sites 1302. As described above, in some embodiments, the pulse sequence 1303 is controlled to have a variation of about 10 parts per million or less. Of course, depending on the analyte desired, the tolerated variation in the pulse sequence 1303 can be greater (or smaller).

In response to the pulse sequence 1300, detectors 1 to n (n being an integer) in a detector 1306 capture optical radiation from the measurement site 1302 and provide respective streams of output signals. Each signal from one of detectors 1-n can be considered a stream having respective time slots corresponding to the optical pulses from emitter sets 1-n in the emitter 1304. Although n emitters and n detectors are shown, the number of emitters and detectors need not be the same in certain implementations.

A front end interface 1308 can accept these multiple streams from detectors 1-n and deliver one or more signals or composite signal(s) back to the signal processor 1310. A stream from the detectors 1-n can thus include measured light intensities corresponding to the light pulses emitted from the emitter 1304.

The signal processor 1310 can then perform various calculations to measure the amount of glucose and other analytes based on these multiple streams of signals. In order to help explain how the signal processor 1310 can measure analytes like glucose, a primer on the spectroscopy employed in these embodiments will now be provided.

Spectroscopy is premised upon the Beer-Lambert law. According to this law, the properties of a material, e.g., glucose present in a measurement site, can be deterministically calculated from the absorption of light traveling through the material. Specifically, there is a logarithmic relation between the transmission of light through a material and the concentration of a substance and also between the transmission and the length of the path traveled by the light. As noted, this relation is known as the Beer-Lambert law.

The Beer-Lambert law is usually written as:

Absorbance $A = m \cdot b \cdot c$, where:

m is the wavelength-dependent molar absorptivity coefficient (usually expressed in units of $M^{-1} \text{ cm}^{-1}$);

b is the mean path length; and

c is the analyte concentration (e.g., the desired parameter).

In spectroscopy, instruments attempt to obtain the analyte concentration (C) by relating absorbance (A) to transmittance (T). Transmittance is a proportional value defined as:

$T = I/I_0$, where:

I is the light intensity measured by the instrument from the measurement site; and

I_0 is the initial light intensity from the emitter.

Absorbance (A) can be equated to the transmittance (T) by the equation:

$$A = -\log T$$

Therefore, substituting equations from above:

$$A = -\log(I/I_0)$$

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In view of this relationship, spectroscopy thus relies on a proportional-based calculation of $-\log(I/I_0)$ and solving for analyte concentration (c).

Typically, in order to simplify the calculations, spectroscopy will use detectors that are at the same location in order to keep the path length (b) a fixed, known constant. In addition, spectroscopy will employ various mechanisms to definitively know the transmission power (I_0), such as a photodiode located at the light source. This architecture can be viewed as a single channel or single stream sensor, because the detectors are at a single location.

However, this scheme can encounter several difficulties in measuring analytes, such as glucose. This can be due to the high overlap of absorption of light by water at the wavelengths relevant to glucose as well as other factors, such as high self-noise of the components.

Embodiments of the present disclosure can employ a different approach that in part allows for the measurement of analytes like glucose. Some embodiments can employ a bulk, non-pulsatile measurement in order to confirm or validate a pulsatile measurement. In addition, both the non-pulsatile and pulsatile measurements can employ, among other things, the multi-stream operation described above in order to attain sufficient SNR. In particular, a single light source having multiple emitters can be used to transmit light to multiple detectors having a spatial configuration.

A single light source having multiple emitters can allow for a range of wavelengths of light to be used. For example, visible, infrared, and near infrared wavelengths can be employed. Varying powers of light intensity for different wavelengths can also be employed.

Secondly, the use of multiple-detectors in a spatial configuration allow for a bulk measurement to confirm or validate that the sensor is positioned correctly. This is because the multiple locations of the spatial configuration can provide, for example, topology information that indicates where the sensor has been positioned. Currently available sensors do not provide such information. For example, if the bulk measurement is within a predetermined range of values, then this can indicate that the sensor is positioned correctly in order to perform pulsatile measurements for analytes like glucose. If the bulk measurement is outside of a certain range or is an unexpected value, then this can indicate that the sensor should be adjusted, or that the pulsatile measurements can be processed differently to compensate, such as using a different calibration curve or adjusting a calibration curve. This feature and others allow the embodiments to achieve noise cancellation and noise reduction, which can be several times greater in magnitude than what is achievable by currently available technology.

In order to help illustrate aspects of the multi-stream measurement approach, the following example derivation is provided. Transmittance (T) can be expressed as:

$$T = e^{-m \cdot b \cdot c}$$

In terms of light intensity, this equation can also be rewritten as:

$$I/I_0 = e^{-m \cdot b \cdot c}$$

Or, at a detector, the measured light (I) can be expressed as:

$$I = I_0 \cdot e^{-m \cdot b \cdot c}$$

As noted, in the present disclosure, multiple detectors (1 to n) can be employed, which results in $I_1 \dots I_n$ streams of measurements. Assuming each of these detectors have their

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own path lengths, $b_1 \dots b_n$, from the light source, the measured light intensities can be expressed as:

$$I_n = I_o * e^{-m * b_n * c}$$

The measured light intensities at any two different detectors can be referenced to each other. For example:

$$I_1/I_n = (I_o * e^{-m * b_1 * c}) / (I_o * e^{-m * b_n * c})$$

As can be seen, the terms, I_o , cancel out and, based on exponent algebra, the equation can be rewritten as:

$$I_1/I_n = e^{-m(b_1 - b_n)c}$$

From this equation, the analyte concentration (c) can now be derived from bulk signals $I_1 \dots I_n$ and knowing the respective mean path lengths b_1 and b_n . This scheme also allows for the cancelling out of I_o , and thus, noise generated by the emitter **1304** can be cancelled out or reduced. In addition, since the scheme employs a mean path length difference, any changes in mean path length and topological variations from patient to patient are easily accounted. Furthermore, this bulk-measurement scheme can be extended across multiple wavelengths. This flexibility and other features allow embodiments of the present disclosure to measure blood analytes like glucose.

For example, as noted, the non-pulsatile, bulk measurements can be combined with pulsatile measurements to more accurately measure analytes like glucose. In particular, the non-pulsatile, bulk measurement can be used to confirm or validate the amount of glucose, protein, etc. in the pulsatile measurements taken at the tissue at the measurement site(s) **1302**. The pulsatile measurements can be used to measure the amount of glucose, hemoglobin, or the like that is present in the blood. Accordingly, these different measurements can be combined to thus determine analytes like blood glucose.

FIG. **14A** illustrates an embodiment of a detector submount **1400a** positioned beneath the partially cylindrical protrusion **605** of FIG. **6** (or alternatively, the protrusion **605b**). The detector submount **1400a** includes two rows **1408a** of detectors **1410a**. The partially cylindrical protrusion **605** can facilitate reducing the number and/or size of detectors used in a sensor because the protrusion **605** can act as a lens that focuses light onto a smaller area.

To illustrate, in some sensors that do not include the partially cylindrical protrusion **605**, sixteen detectors can be used, including four rows of four detectors each. Multiple rows of detectors can be used to measure certain analytes, such as glucose or total hemoglobin, among others. Multiple rows of detectors can also be used to detect light piping (e.g., light that bypasses the measurement site). However, using more detectors in a sensor can add cost, complexity, and noise to the sensor.

Applying the partially cylindrical protrusion **605** to such a sensor, however, could reduce the number of detectors or rows of detectors used while still receiving the substantially same amount of light, due to the focusing properties of the protrusion **605** (see FIG. **14B**). This is the example situation illustrated in FIG. **14**—two rows **1408a** of detectors **1410a** are used instead of four. Advantageously, in certain embodiments, the resulting sensor can be more cost effective, have less complexity, and have an improved SNR, due to fewer and/or smaller photodiodes.

In other embodiments, using the partially cylindrical protrusion **605** can allow the number of detector rows to be reduced to one or three rows of four detectors. The number of detectors in each row can also be reduced. Alternatively, the number of rows might not be reduced but the size of the

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detectors can be reduced. Many other configurations of detector rows and sizes can also be provided.

FIG. **14B** depicts a front elevation view of the partially cylindrical protrusion **605** (or alternatively, the protrusion **605b**) that illustrates how light from emitters (not shown) can be focused by the protrusion **605** onto detectors. The protrusion **605** is placed above a detector submount **1400b** having one or more detectors **1410b** disposed thereon. The submount **1400b** can include any number of rows of detectors **1410**, although one row is shown.

Light, represented by rays **1420**, is emitted from the emitters onto the protrusion **605**. These light rays **1420** can be attenuated by body tissue (not shown). When the light rays **1420** enter the protrusion **605**, the protrusion **605** acts as a lens to refract the rays into rays **1422**. This refraction is caused in certain embodiments by the partially cylindrical shape of the protrusion **605**. The refraction causes the rays **1422** to be focused or substantially focused on the one or more detectors **1410b**. Since the light is focused on a smaller area, a sensor including the protrusion **605** can include fewer detectors to capture the same amount of light compared with other sensors.

FIG. **14C** illustrates another embodiment of a detector submount **1400c**, which can be disposed under the protrusion **605b** (or alternatively, the protrusion **605**). The detector submount **1400c** includes a single row **1408c** of detectors **1410c**. The detectors are electrically connected to conductors **1412c**, which can be gold, silver, copper, or any other suitable conductive material.

The detector submount **1400c** is shown positioned under the protrusion **605b** in a detector subassembly **1450** illustrated in FIG. **14D**. A top-down view of the detector subassembly **1450** is also shown in FIG. **14E**. In the detector subassembly **1450**, a cylindrical housing **1430** is disposed on the submount **1400c**. The cylindrical housing **1430** includes a transparent cover **1432**, upon which the protrusion **605b** is disposed. Thus, as shown in FIG. **14D**, a gap **1434** exists between the detectors **1410c** and the protrusion **605b**. The height of this gap **1434** can be chosen to increase or maximize the amount of light that impinges on the detectors **1410c**.

The cylindrical housing **1430** can be made of metal, plastic, or another suitable material. The transparent cover **1432** can be fabricated from glass or plastic, among other materials. The cylindrical housing **1430** can be attached to the submount **1400c** at the same time or substantially the same time as the detectors **1410c** to reduce manufacturing costs. A shape other than a cylinder can be selected for the housing **1430** in various embodiments.

In certain embodiments, the cylindrical housing **1430** (and transparent cover **1432**) forms an airtight or substantially airtight or hermetic seal with the submount **1400c**. As a result, the cylindrical housing **1430** can protect the detectors **1410c** and conductors **1412c** from fluids and vapors that can cause corrosion. Advantageously, in certain embodiments, the cylindrical housing **1430** can protect the detectors **1410c** and conductors **1412c** more effectively than currently-available resin epoxies, which are sometimes applied to solder joints between conductors and detectors.

In embodiments where the cylindrical housing **1430** is at least partially made of metal, the cylindrical housing **1430** can provide noise shielding for the detectors **1410c**. For example, the cylindrical housing **1430** can be soldered to a ground connection or ground plane on the submount **1400c**, which allows the cylindrical housing **1430** to reduce noise. In another embodiment, the transparent cover **1432** can include a conductive material or conductive layer, such as

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conductive glass or plastic. The transparent cover **1432** can include any of the features of the noise shields **790** described above.

The protrusion **605b** includes the chamfered edges **607** described above with respect to FIG. 6E. These chamfered edges **607** can allow a patient to more comfortably slide a finger over the protrusion **605b** when inserting the finger into the sensor **301f**.

FIG. 14F illustrates a portion of the detector shell **306f**, which includes the detectors **1410c** on the substrate **1400c**. The substrate **1400c** is enclosed by a shielding enclosure **1490**, which can include the features of the shielding enclosures **790a**, **790b** described above (see also FIG. 17). The shielding enclosure **1490** can be made of metal. The shielding enclosure **1490** includes a window **1492a** above the detectors **1410c**, which allows light to be transmitted onto the detectors **1410c**.

A noise shield **1403** is disposed above the shielding enclosure **1490**. The noise shield **1403**, in the depicted embodiment, includes a window **1492a** corresponding to the window **1492a**. Each of the windows **1492a**, **1492b** can include glass, plastic, or can be an opening without glass or plastic. In some embodiments, the windows **1492a**, **1492b** may be selected to have different sizes or shapes from each other.

The noise shield **1403** can include any of the features of the conductive glass described above. In the depicted embodiment, the noise shield **1403** extends about three-quarters of the length of the detector shell **306f**. In other embodiments, the noise shield **1403** could be smaller or larger. The noise shield **1403** could, for instance, merely cover the detectors **1410c**, the submount **1400c**, or a portion thereof. The noise shield **1403** also includes a stop **1413** for positioning a measurement site within the sensor **301f**. Advantageously, in certain embodiments, the noise shield **1403** can reduce noise caused by light piping.

A thermistor **1470** is also shown. The thermistor **1470** is attached to the submount **1400c** and protrudes above the noise shield **1403**. As described above, the thermistor **1470** can be employed to measure a temperature of a measurement site. Such a temperature can be helpful in correcting for wavelength drift due to changes in water absorption, which can be temperature dependent, thereby providing more accurate data useful in detecting blood analytes like glucose.

In the depicted embodiment, the detectors **1410c** are not enclosed in the cylindrical housing **1430**. In an alternative embodiment, the cylindrical housing **1430** encloses the detectors **1410c** and is disposed under the noise shield **1403**. In another embodiment, the cylindrical housing **1430** encloses the detectors **1410c** and the noise shield **1403** is not used. If both the cylindrical housing **1403** and the noise shield **1403** are used, either or both can have noise shielding features.

FIG. 14G illustrates the detector shell **306f** of FIG. 14F, with the finger bed **310f** disposed thereon. FIG. 14H illustrates the detector shell **306f** of FIG. 14G, with the protrusion **605b** disposed in the finger bed **310f**.

FIG. 14I illustrates a cutaway view of the sensor **301f**. Not all features of the sensor **301f** are shown, such as the protrusion **605b**. Features shown include the emitter and detector shells **304f**, **306f**, the flaps **307f**, the heat sink **350f** and fins **351f**, the finger bed **310f**, and the noise shield **1403**.

In addition to these features, emitters **1404** are depicted in the emitter shell **304f**. The emitters **1404** are disposed on a submount **1401**, which is connected to a circuit board **1419**. The emitters **1404** are also enclosed within a cylindrical

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housing **1480**. The cylindrical housing **1480** can include all of the features of the cylindrical housing **1430** described above. For example, the cylindrical housing **1480** can be made of metal, can be connected to a ground plane of the submount **1401** to provide noise shielding, and can include a transparent cover **1482**.

The cylindrical housing **1480** can also protect the emitters **1404** from fluids and vapors that can cause corrosion. Moreover, the cylindrical housing **1480** can provide a gap between the emitters **1404** and the measurement site (not shown), which can allow light from the emitters **1404** to even out or average out before reaching the measurement site.

The heat sink **350f**, in addition to including the fins **351f**, includes a protuberance **352f** that extends down from the fins **351f** and contacts the submount **1401**. The protuberance **352f** can be connected to the submount **1401**, for example, with thermal paste or the like. The protuberance **352f** can sink heat from the emitters **1404** and dissipate the heat via the fins **351f**.

FIGS. 15A and 15B illustrate embodiments of sensor portions **1500A**, **1500B** that include alternative heat sink features to those described above. These features can be incorporated into any of the sensors described above. For example, any of the sensors above can be modified to use the heat sink features described below instead of or in addition to the heat sink features of the sensors described above.

The sensor portions **1500A**, **1500B** shown include LED emitters **1504**; however, for ease of illustration, the detectors have been omitted. The sensor portions **1500A**, **1500B** shown can be included, for example, in any of the emitter shells described above.

The LEDs **1504** of the sensor portions **1500A**, **1500B** are connected to a substrate or submount **1502**. The submount **1502** can be used in place of any of the submounts described above. The submount **1502** can be a non-electrically conducting material made of any of a variety of materials, such as ceramic, glass, or the like. A cable **1512** is attached to the submount **1502** and includes electrical wiring **1514**, such as twisted wires and the like, for communicating with the LEDs **1504**. The cable **1512** can correspond to the cables **212** described above.

Although not shown, the cable **1512** can also include electrical connections to a detector. Only a portion of the cable **1512** is shown for clarity. The depicted embodiment of the cable **1512** includes an outer jacket **1510** and a conductive shield **1506** disposed within the outer jacket **1510**. The conductive shield **1506** can be a ground shield or the like that is made of a metal such as braided copper or aluminum. The conductive shield **1506** or a portion of the conductive shield **1506** can be electrically connected to the submount **1502** and can reduce noise in the signal generated by the sensor **1500A**, **1500B** by reducing RF coupling with the wires **1514**. In alternative embodiments, the cable **1512** does not have a conductive shield. For example, the cable **1512** could be a twisted pair cable or the like, with one wire of the twisted pair used as a heat sink.

Referring specifically to FIG. 15A, in certain embodiments, the conductive shield **1506** can act as a heat sink for the LEDs **1504** by absorbing thermal energy from the LEDs **1504** and/or the submount **1502**. An optional heat insulator **1520** in communication with the submount **1502** can also assist with directing heat toward the conductive shield **1506**. The heat insulator **1520** can be made of plastic or another suitable material. Advantageously, using the conductive shield **1506** in the cable **1512** as a heat sink can, in certain embodiments, reduce cost for the sensor.

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Referring to FIG. 15B, the conductive shield 1506 can be attached to both the submount 1502 and to a heat sink layer 1530 sandwiched between the submount 1502 and the optional insulator 1520. Together, the heat sink layer 1530 and the conductive shield 1506 in the cable 1512 can absorb at least part of the thermal energy from the LEDs and/or the submount 1502.

FIGS. 15C and 15D illustrate implementations of a sensor portion 1500C that includes the heat sink features of the sensor portion 1500A described above with respect to FIG. 15A. The sensor portion 1500C includes the features of the sensor portion 1500A, except that the optional insulator 1520 is not shown. FIG. 15D is a side cutaway view of the sensor portion 1500C that shows the emitters 1504.

The cable 1512 includes the outer jacket 1510 and the conductive shield 1506. The conductive shield 1506 is soldered to the submount 1502, and the solder joint 1561 is shown. In some embodiments, a larger solder joint 1561 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, a cylindrical housing 1580, corresponding to the cylindrical housing 1480 of FIG. 14I, is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15E and 15F illustrate implementations of a sensor portion 1500E that includes the heat sink features of the sensor portion 1500B described above with respect to FIG. 15B. The sensor portion 1500E includes the heat sink layer 1530. The heat sink layer 1530 can be a metal plate, such as a copper plate or the like. The optional insulator 1520 is not shown. FIG. 15F is a side cutaway view of the sensor portion 1500E that shows the emitters 1504.

In the depicted embodiment, the conductive shield 1506 of the cable 1512 is soldered to the heat sink layer 1530 instead of the submount 1502. The solder joint 1565 is shown. In some embodiments, a larger solder joint 1565 can assist with removing heat more rapidly from the emitters 1504. Various connections 1563 between the submount 1502 and a circuit board 1519 are shown. In addition, the cylindrical housing 1580 is shown protruding through the circuit board 1519. The emitters 1504 are enclosed in the cylindrical housing 1580.

FIGS. 15G and 15H illustrate embodiments of connector features that can be used with any of the sensors described above with respect to FIGS. 1 through 15F. Referring to FIG. 15G, the circuit board 1519 includes a female connector 1575 that mates with a male connector 1577 connected to a daughter board 1587. The daughter board 1587 includes connections to the electrical wiring 1514 of the cable 1512. The connected boards 1519, 1587 are shown in FIG. 15H. Also shown is a hole 1573 that can receive the cylindrical housing 1580 described above.

Advantageously, in certain embodiments, using a daughter board 1587 to connect to the circuit board 1519 can enable connections to be made more easily to the circuit board 1519. In addition, using separate boards can be easier to manufacture than a single circuit board 1519 with all connections soldered to the circuit board 1519.

FIG. 15I illustrates an exemplary architecture for front-end interface 108 as a transimpedance-based front-end. As noted, front-end interfaces 108 provide an interface that adapts the output of detectors 106 into a form that can be handled by signal processor 110. As shown in this figure, sensor 101 and front-end interfaces 108 may be integrated together as a single component, such as an integrated circuit. Of course, one skilled in the art will recognize that sensor

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101 and front end interfaces 108 may comprise multiple components or circuits that are coupled together.

Front-end interfaces 108 may be implemented using transimpedance amplifiers that are coupled to analog to digital converters in a sigma delta converter. In some embodiments, a programmable gain amplifier (PGA) can be used in combination with the transimpedance-based front-ends. For example, the output of a transimpedance-based front-end may be output to a sigma-delta ADC that comprises a PGA. A PGA may be useful in order to provide another level of amplification and control of the stream of signals from detectors 106. The PGA may be an integrated circuit or built from a set of micro-relays. Alternatively, the PGA and ADC components in converter 900 may be integrated with the transimpedance-based front-end in sensor 101.

Due to the low-noise requirements for measuring blood analytes like glucose and the challenge of using multiple photodiodes in detector 106, the applicants developed a noise model to assist in configuring front-end 108. Conventionally, those skilled in the art have focused on optimizing the impedance of the transimpedance amplifiers to minimize noise.

However, the following noise model was discovered by the applicants:

$$\text{Noise} = \sqrt{aR + bR^2},$$

where:

aR is characteristic of the impedance of the transimpedance amplifier; and

bR^2 is characteristic of the impedance of the photodiodes in detector and the number of photodiodes in detector 106.

The foregoing noise model was found to be helpful at least in part due to the high SNR required to measure analytes like glucose. However, the foregoing noise model was not previously recognized by artisans at least in part because, in conventional devices, the major contributor to noise was generally believed to originate from the emitter or the LEDs. Therefore, artisans have generally continued to focus on reducing noise at the emitter.

However, for analytes like glucose, the discovered noise model revealed that one of the major contributors to noise was generated by the photodiodes. In addition, the amount of noise varied based on the number of photodiodes coupled to a transimpedance amplifier. Accordingly, combinations of various photodiodes from different manufacturers, different impedance values with the transimpedance amplifiers, and different numbers of photodiodes were tested as possible embodiments.

In some embodiments, different combinations of transimpedance to photodiodes may be used. For example, detectors 1-4 (as shown, e.g., in FIG. 12A) may each comprise four photodiodes. In some embodiments, each detector of four photodiodes may be coupled to one or more transimpedance amplifiers. The configuration of these amplifiers may be set according to the model shown in FIG. 15J.

Alternatively, each of the photodiodes may be coupled to its own respective transimpedance amplifier. For example, transimpedance amplifiers may be implemented as integrated circuits on the same circuit board as detectors 1-4. In this embodiment, the transimpedance amplifiers may be grouped into an averaging (or summing) circuit, which are known to those skilled in the art, in order to provide an output stream from the detector. The use of a summing

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amplifier to combine outputs from several transimpedance amplifiers into a single, analog signal may be helpful in improving the SNR relative to what is obtainable from a single transimpedance amplifier. The configuration of the transimpedance amplifiers in this setting may also be set according to the model shown in FIG. 15J.

As yet another alternative, as noted above with respect to FIGS. 12E through 12H, the photodiodes in detectors 106 may comprise multiple active areas that are grouped together. In some embodiments, each of these active areas may be provided its own respective transimpedance. This form of pairing may allow a transimpedance amplifier to be better matched to the characteristics of its corresponding photodiode or active area of a photodiode.

As noted, FIG. 15J illustrates an exemplary noise model that may be useful in configuring transimpedance amplifiers. As shown, for a given number of photodiodes and a desired SNR, an optimal impedance value for a transimpedance amplifier could be determined.

For example, an exemplary “4 PD per stream” sensor 1502 is shown where detector 106 comprises four photodiodes 1502. The photodiodes 1502 are coupled to a single transimpedance amplifier 1504 to produce an output stream 1506. In this example, the transimpedance amplifier comprises 10 MO resistors 1508 and 1510. Thus, output stream 1506 is produced from the four photodiodes (PD) 1502. As shown in the graph of FIG. 15J, the model indicates that resistance values of about 10 MO may provide an acceptable SNR for analytes like glucose.

However, as a comparison, an exemplary “1 PD per stream” sensor 1512 is also shown in FIG. 15J. In particular, sensor 1512 may comprise a plurality of detectors 106 that each comprises a single photodiode 1514. In addition, as shown for this example configuration, each of photodiodes 1514 may be coupled to respective transimpedance amplifiers 1516, e.g., 1 PD per stream. Transimpedance amplifiers are shown having 40 MO resistors 1518. As also shown in the graph of FIG. 15J, the model illustrates that resistance values of 40 MO for resistors 1518 may serve as an alternative to the 4 photodiode per stream architecture of sensor 1502 described above and yet still provide an equivalent SNR.

Moreover, the discovered noise model also indicates that utilizing a 1 photodiode per stream architecture like that in sensor 1512 may provide enhanced performance because each of transimpedance amplifiers 1516 can be tuned or optimized to its respective photodiodes 1518. In some embodiments, an averaging component 1520 may also be used to help cancel or reduce noise across photodiodes 1518.

For purposes of illustration, FIG. 15K shows different architectures (e.g., four PD per stream and one PD per stream) for various embodiments of a sensor and how components of the sensor may be laid out on a circuit board or substrate. For example, sensor 1522 may comprise a “4 PD per stream” architecture on a submount 700 in which each detector 106 comprises four (4) photodiodes 1524. As shown for sensor 1522, the output of each set of four photodiodes 1524 is then aggregated into a single transimpedance amplifier 1526 to produce a signal.

As another example, a sensor 1528 may comprise a “1 PD per stream” architecture on submount 700 in which each detector 106 comprises four (4) photodiodes 1530. In sensor 1528, each individual photodiode 1530 is coupled to a respective transimpedance amplifier 1532. The output of the amplifiers 1532 may then be aggregated into averaging circuit 1520 to produce a signal.

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As noted previously, one skilled in the art will recognize that the photodiodes and detectors may be arranged in different fashions to optimize the detected light. For example, sensor 1534 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1536 arranged in a linear fashion. Likewise, sensor 1538 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1540 arranged in a linear fashion.

Alternatively, sensor 1542 illustrates an exemplary “4 PD per stream” sensor in which the detectors 106 comprise photodiodes 1544 arranged in a two-dimensional pattern, such as a zig-zag pattern. Sensor 1546 illustrates an exemplary “1 PD per stream” sensor in which the detectors comprise photodiodes 1548 also arranged in a zig-zag pattern.

FIG. 15L illustrates an exemplary architecture for a switched-capacitor-based front-end. As shown, front-end interfaces 108 may be implemented using switched capacitor circuits and any number of front-end interfaces 108 may be implemented. The output of these switched capacitor circuits may then be provided to a digital interface 1000 and signal processor 110. Switched capacitor circuits may be useful in system 100 for their resistor free design and analog averaging properties. In particular, the switched capacitor circuitry provides for analog averaging of the signal that allows for a lower smaller sampling rate (e.g., 2 KHz sampling for analog versus 48 KHz sampling for digital designs) than similar digital designs. In some embodiments, the switched capacitor architecture in front end interfaces 108 may provide a similar or equivalent SNR to other front end designs, such as a sigma delta architecture. In addition, a switched capacitor design in front end interfaces 108 may require less computational power by signal processor 110 to perform the same amount of decimation to obtain the same SNR.

FIGS. 16A and 16B illustrate embodiments of disposable optical sensors 1600. In an embodiment, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be incorporated into the disposable sensors 1600 shown. For instance, the sensors 1600 can be used as the sensors 101 in the system 100 described above with respect to FIG. 1. Moreover, any of the features described above, such as protrusion, shielding, and/or heat sink features, can be implemented in other disposable sensor designs that are not depicted herein.

The sensors 1600 include an adult/pediatric sensor 1610 for finger placement and a disposable infant/neonate sensor 1602 configured for toe, foot or hand placement. Each sensor 1600 has a tape end 1610 and an opposite connector end 1620 electrically and mechanically interconnected via a flexible coupling 1630. The tape end 1610 attaches an emitter and detector to a tissue site. Although not shown, the tape end 1610 can also include any of the protrusion, shielding, and/or heat sink features described above. The emitter illuminates the tissue site and the detector generates a sensor signal responsive to the light after tissue absorption, such as absorption by pulsatile arterial blood flow within the tissue site.

The sensor signal is communicated via the flexible coupling 1630 to the connector end 1620. The connector end 1620 can mate with a cable (not shown) that communicates the sensor signal to a monitor (not shown), such as any of the cables or monitors shown above with respect to FIGS. 2A through 2D. Alternatively, the connector end 1620 can mate directly with the monitor.

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FIG. 17 illustrates an exploded view of certain of the components of the sensor 301f described above. A heat sink 1751 and a cable 1781 attach to an emitter shell 1704. The emitter shell attaches to a flap housing 1707. The flap housing 1707 includes a receptacle 1709 to receive a cylindrical housing 1480/1580 (not shown) attached to an emitter submount 1702, which is attached to a circuit board 1719.

A spring 1787 attaches to a detector shell 1706 via pins 1783, 1785, which hold the emitter and detector shells 1704, 1706 together. A support structure 1791 attaches to the detector shell 1706, which provides support for a shielding enclosure 1790. A noise shield 1713 attaches to the shielding enclosure 1790. A detector submount 1700 is disposed inside the shielding enclosure 1790. A finger bed 1710 provides a surface for placement of the patient's finger. Finger bed 1710 may comprise a gripping surface or gripping features, which may assist in placing and stabilizing a patient's finger in the sensor. A partially cylindrical protrusion 1705 may also be disposed in the finger bed 1710. As shown, finger bed 1710 attaches to the noise shield 1703. The noise shield 1703 may be configured to reduce noise, such as from ambient light and electromagnetic noise. For example, the noise shield 1703 may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping.

Noise shield 1703 may also comprise a thermistor 1712. The thermistor 1712 may be helpful in measuring the temperature of a patient's finger. For example, the thermistor 1712 may be useful in detecting when the patient's finger is reaching an unsafe temperature that is too hot or too cold. In addition, the temperature of the patient's finger may be useful in indicating to the sensor the presence of low perfusion as the temperature drops. In addition, the thermistor 1712 may be useful in detecting a shift in the characteristics of the water spectrum in the patient's finger, which can be temperature dependent.

Moreover, a flex circuit cover 1706 attaches to the pins 1783, 1785. Although not shown, a flex circuit can also be provided that connects the circuit board 1719 with the submount 1700 (or a circuit board to which the submount 1700 is connected). A flex circuit protector 1760 may be provided to provide a barrier or shield to the flex circuit (not shown). In particular, the flex circuit protector 1760 may also prevent any electrostatic discharge to or from the flex circuit. The flex circuit protector 1760 may be constructed from well known materials, such as a plastic or rubber materials.

FIG. 18 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a pure water ex-vivo sample. In particular, ten samples were prepared that ranged from 0-55 mg/dL. Two samples were used as a training set and eight samples were then used as a test population. As shown, embodiments of the sensor 101 were able to obtain at least a standard deviation of 13 mg/dL in the training set and 11 mg/dL in the test population.

FIG. 19 shows the results obtained by an exemplary sensor 101 of the present disclosure that was configured for measuring glucose. This sensor 101 was tested using a turbid ex-vivo sample. In particular, 25 samples of water/glucose/Liposyn were prepared that ranged from 0-55 mg/dL. Five samples were used as a training set and 20 samples were then used as a test population. As shown, embodiments of sensor 101 were able to obtain at least a standard deviation of 37 mg/dL in the training set and 32 mg/dL in the test population.

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FIGS. 20 through 22 shows other results that can be obtained by an embodiment of system 100. In FIG. 20, 150 blood samples from two diabetic adult volunteers were collected over a 10-day period. Invasive measurements were taken with a YSI glucometer to serve as a reference measurement. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs and four independent detector streams. As shown, the system 100 obtained a correlation of about 85% and Arms of about 31 mg/dL.

In FIG. 21, 34 blood samples were taken from a diabetic adult volunteer collected over a 2-day period. Invasive measurements were also taken with a glucometer for comparison. Noninvasive measurements were then taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106. As shown, the system 100 was able to attain a correlation of about 90% and Arms of about 22 mg/dL.

The results shown in FIG. 22 relate to total hemoglobin testing with an exemplary sensor 101 of the present disclosure. In particular, 47 blood samples were collected from nine adult volunteers. Invasive measurements were then taken with a CO-oximeter for comparison. Noninvasive measurements were taken with an embodiment of system 100 that comprised four LEDs in emitter 104 and four independent detector channels from detectors 106. Measurements were averaged over 1 minute. As shown, the testing resulted in a correlation of about 93% and Arms of about 0.8 mg/dL.

Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

While certain embodiments of the inventions disclosed herein have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Indeed, the novel methods and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods and systems described herein can be made without departing from the spirit of the inventions disclosed herein. The claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of certain of the inventions disclosed herein.

What is claimed is:

1. A noninvasive physiological parameter measurement device adapted to be worn by a wearer, the noninvasive physiological parameter measurement device comprising:

- one or more light emitters;
- a substrate having a surface;
- a first set of photodiodes arranged on the surface and spaced apart from each other, wherein:
 - the first set of photodiodes comprises at least four photodiodes, and
 - the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first

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signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue;

a second set of photodiodes arranged on the surface and spaced apart from each other, wherein:

the second set of photodiodes comprises at least four photodiodes,

the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue, and

at least one of the first signal stream or the second signal stream includes information usable to determine a physiological parameter of a wearer of the noninvasive physiological parameter measurement device;

a wall extending from the surface and configured to surround at least the first and second sets of photodiodes; and

a cover arranged to cover at least a portion of the surface of the substrate, wherein the cover comprises a protrusion that extends over all of the photodiodes of the first and second sets of photodiodes arranged on the surface, and wherein the cover is further configured to cover the wall.

2. The noninvasive physiological parameter measurement device of claim 1 further comprising preprocessing electronics including at least:

first preprocessing electronics configured to preprocess the first signal stream; and

second preprocessing electronics configured to preprocess the second signal stream.

3. The noninvasive physiological parameter measurement device of claim 2, wherein:

the first preprocessing electronics comprise at least a first amplifier configured to receive the first signal stream and at least amplify the first signal stream, and

the second preprocessing electronics comprise at least a second amplifier configured to receive the second signal stream and at least amplify the second signal stream.

4. The noninvasive physiological parameter measurement device of claim 3, wherein the preprocessing further comprises converting at least one of the first signal stream or the second signal stream from analog to digital.

5. The noninvasive physiological parameter measurement device of claim 3, wherein the protrusion comprises a convex protrusion, and wherein at least a portion of the cover is comprised of a sufficiently rigid material to cause tissue of the wearer to conform to at least a portion of a shape of the cover.

6. The noninvasive physiological parameter measurement device of claim 5, wherein the physiological parameter comprises at least one of: pulse rate, glucose, oxygen, oxygen saturation, methemoglobin, total hemoglobin, carboxyhemoglobin, or carbon monoxide.

7. The noninvasive physiological parameter measurement device of claim 6, wherein at least part of the cover is light permeable.

8. The noninvasive physiological parameter measurement device of claim 6 further comprising:

one or more openings that allow light to pass through to the photodiodes of the first and second sets of photodiodes.

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9. The noninvasive physiological parameter measurement device of claim 8, wherein the wall operably connects to the substrate on one side and operably connects to the cover on an opposite side.

10. The noninvasive physiological parameter measurement device of claim 9 further comprising:

a touch-screen display;

a strap configured to facilitate attachment of at least part of the noninvasive physiological parameter measurement device to an arm of the wearer; and

one or more processors configured to:

receive information responsive to at least one of the first signal stream or the second signal stream;

process the information to determine physiological parameter measurement information; and

cause communication of the physiological parameter measurement information to a user interface displayed on the touch-screen display.

11. The noninvasive physiological parameter measurement device of claim 10, wherein the attenuated light is reflected by the tissue.

12. The noninvasive physiological parameter measurement device of claim 11, wherein the one or more processors are further configured to:

cause transmission of the physiological parameter measurement information to at least one of: a mobile phone, or a computer network.

13. The noninvasive physiological parameter measurement device of claim 12 further comprising:

a magnet configured to be used as a connecting mechanism.

14. A noninvasive physiological parameter measurement device comprising:

one or more light emitters;

a first set of photodiodes, the first set of photodiodes comprising at least four photodiodes, the photodiodes of the first set of photodiodes connected to one another in parallel to provide a first signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue;

a second set of photodiodes, the second set of photodiodes comprising at least four photodiodes, the photodiodes of the second set of photodiodes connected to one another in parallel to provide a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue;

a wall configured to surround at least the first and second sets of photodiodes;

a protrusion that extends over the wall and the photodiodes of the first and second sets of photodiodes; and

one or more processors configured to:

receive information responsive to at least one of the first signal stream or the second signal stream; and

process the information to determine physiological parameter measurement information.

15. The noninvasive physiological parameter measurement device of claim 14, wherein the first and second sets of photodiodes are arranged on a substrate, and wherein the protrusion extends over at least a part of the substrate.

16. The noninvasive physiological parameter measurement device of claim 15 further comprising preprocessing electronics including at least:

first preprocessing electronics configured to preprocess the first signal stream; and

second preprocessing electronics configured to preprocess the second signal stream,

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wherein the information responsive to the at least one of the first signal stream or the second signal stream is received by the one or more processors after preprocessing of the at least one of the first signal stream or the second signal stream.

17. The noninvasive physiological parameter measurement device of claim 16, wherein:

the first preprocessing electronics comprise at least a first amplifier configured to receive the first signal stream and at least amplify the first signal stream, and the second preprocessing electronics comprise at least a second amplifier configured to receive the second signal stream and at least amplify the second signal stream.

18. The noninvasive physiological parameter measurement device of claim 17, wherein the preprocessing further comprises converting at least one of the first signal stream or the second signal stream from analog to digital.

19. The noninvasive physiological parameter measurement device of claim 17, wherein the protrusion comprises a convex protrusion, and wherein at least a portion of the convex protrusion is comprised of a sufficiently rigid material to cause tissue of a wearer of the noninvasive physiological parameter measurement device to conform to at least a portion of a shape of the convex protrusion when the noninvasive physiological parameter measurement device is worn by the wearer.

20. The noninvasive physiological parameter measurement device of claim 19, wherein the physiological parameter comprises at least one of: pulse rate, glucose, oxygen, oxygen saturation, methemoglobin, total hemoglobin, carboxyhemoglobin, or carbon monoxide.

21. The noninvasive physiological parameter measurement device of claim 20, wherein at least part of the protrusion is light permeable.

22. The noninvasive physiological parameter measurement device of claim 20 further comprising:

one or more openings that allow light to pass through to the photodiodes of the first and second sets of photodiodes.

23. The noninvasive physiological parameter measurement device of claim 22 further comprising:

a strap configured to facilitate attachment of at least part of the noninvasive physiological parameter measurement device to an arm of the wearer; and

a touch-screen display,

wherein the one or more processors are further configured to cause communication of the physiological parameter measurement information to a user interface displayed on the touch-screen display.

24. The noninvasive physiological parameter measurement device of claim 23, wherein the attenuated light is reflected by the tissue.

25. The noninvasive physiological parameter measurement device of claim 24, wherein the one or more processors are further configured to:

cause transmission of the physiological parameter measurement information to at least one of: a mobile phone, or a computer network.

26. A physiological measurement system comprising:

a noninvasive physiological parameter measurement device according to claim 25; and

a mobile phone configured to wirelessly communicate with the noninvasive physiological parameter measurement device.

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27. A noninvasive physiological parameter measurement device adapted to be worn by a wearer, the noninvasive physiological parameter measurement device comprising:

one or more light emitters;

a substrate having a surface;

a first set of photodiodes arranged on the surface and spaced apart from each other, wherein:

the first set of photodiodes comprises at least four photodiodes, and

the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue;

a second set of photodiodes arranged on the surface and spaced apart from each other, wherein:

the second set of photodiodes comprises at least four photodiodes,

the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream responsive to light from at least one of the one or more light emitters attenuated by body tissue,

at least one of the first signal stream or the second signal stream includes information usable to determine a physiological parameter of a wearer of the noninvasive physiological parameter measurement device, and

the physiological parameter comprises at least one of: pulse rate, glucose, oxygen, oxygen saturation, methemoglobin, total hemoglobin, carboxyhemoglobin, or carbon monoxide;

first preprocessing electronics configured to preprocess the first signal stream, the first preprocessing electronics comprising at least a first amplifier configured to receive the first signal stream and at least amplify the first signal stream;

second preprocessing electronics configured to preprocess the second signal stream, the second preprocessing electronics comprising at least a second amplifier configured to receive the second signal stream and at least amplify the second signal stream;

a wall extending from the surface and configured to surround at least the first and second sets of photodiodes;

a cover arranged to cover at least a portion of the surface of the substrate, wherein:

the cover comprises a protrusion that extends over all of the photodiodes of the first and second sets of photodiodes arranged on the surface,

the protrusion comprises a convex protrusion,

at least a portion the cover is comprised of a sufficiently rigid material to cause tissue of the wearer to conform to at least a portion of a shape of the cover, the cover is further configured to cover the wall, and the wall operably connects to the substrate on one side and operably connects to the cover on an opposite side;

one or more openings that allow light to pass through to the photodiodes of the first and second sets of photodiodes;

a touch-screen display;

a strap configured to facilitate attachment of at least part of the noninvasive physiological parameter measurement device to an arm of the wearer; and

one or more processors configured to:

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receive information responsive to at least one of the
first signal stream or the second signal stream;
process the information to determine physiological
parameter measurement information;
cause communication of the physiological parameter
measurement information to a user interface dis- 5
played on the touch-screen display; and
cause transmission of the physiological parameter mea-
surement information to at least one of: a mobile
phone, or a computer network. 10

* * * * *

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MASIMO CORPORATION,
Patent Owner/Appellant

v.

APPLE INC.,
Petitioner/Appellee

Appeal Nos. 2022-1972¹
2022-1973
2022-1975
2022-1976

Proceeding Nos.: IPR2020-01713, IPR2020-01716, IPR2020-01733 and IPR2020-01737

NOTICE FORWARDING CERTIFIED LIST

A Notice of Appeal to the United States Court of Appeals for the Federal Circuit was timely filed June 28, 2022, in the United States Patent and Trademark Office in connection with the above identified *Inter Partes Review* proceedings. Pursuant to 35 U.S.C. § 143, a Certified List is this day being forwarded to the Federal Circuit.

Respectfully submitted,

Date: August 9, 2022

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Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

¹ Appeal No. 2022-1972 (Lead) is consolidated with Appeal Nos. 2022-1973, 2022-1975 and 2022-1976 pursuant to Court Order (Dkt. No. 2) and Note to File (Dkt. No. 3) dated July 5, 2022.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing NOTICE
FORWARDING CERTIFIED LIST has been served, via electronic mail, on counsel for Appellant
and Appellee this 9th day of August, 2022, as follows:

<u>PATENT OWNER:</u>	<u>PETITIONER:</u>
Joseph R. Re Jeremiah Helm Stephen C. Jensen Jarom D. Kesler Stephen W. Larson KNOBBE, MARTENS, OLSON & BEAR, LLP joseph.re@knobbe.com jeremiah.helm@knobbe.com steve.jensen@knobbe.com jarom.kesler@knobbe.com stephen.larson@knobbe.com	Lauren Ann Degnan Ashley Bolt Christopher Dryer Walter Karl Renner Adi Williams FISH & RICHARDSON PC degan@fr.com bolt@fr.com dryer@fr.com renner@fr.com awilliams@fr.com

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U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

August 9, 2022

(Date)

THIS IS TO CERTIFY that the attached document is a list of the papers that comprise the record before the Patent Trial and Appeal Board (PTAB) for the *Inter Partes Review* proceeding identified below.

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2020-01713
Patent No. 10,624,564 B1
By authority of the

DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer



Prosecution History ~ IPR2020-01713

Date	Document
9/30/2020	Petition for Inter Partes Review
9/30/2020	Petitioner's Power of Attorney
10/20/2020	Patent Owner's Mandatory Notices
11/10/2020	Notice of Filing Date Accorded to Petition
1/22/2021	Petitioner's Exhibit List
2/10/2021	Patent Owner's Notice of Waiver of Preliminary Response
5/5/2021	Decision - Institution of Inter Partes Review
5/5/2021	Scheduling Order
5/19/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence Submitted Before Trial Institution
6/9/2021	Petitioner's Motion to Submit Supplemental Information
6/14/2021	Order - Motion to Submit Supplemental Information
6/21/2021	Petitioner's Submission of Supplemental Information
6/29/2021	Notice of Deposition - Kenny, Ph.D.
8/4/2021	Patent Owner's Response to Petition
8/4/2021	Patent Owner's Exhibit List
8/11/2021	Petitioner's Objections to Evidence
9/13/2021	Petitioner's Updated Mandatory Notice
10/27/2021	Petitioner's Reply to Patent Owner's Response
11/3/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence
11/17/2021	Notice of Deposition - Kenny, Ph.D.
12/8/2021	Patent Owner's Sur-Reply
12/8/2021	Patent Owner's Updated Exhibit List
12/29/2021	Petitioner's Request for Oral Hearing
12/29/2021	Patent Owner's Request for Oral Argument
1/5/2022	Order: Setting Oral Argument
1/21/2022	Patent Owner's Mandatory Notice Updating Counsel Information
2/4/2022	Patent Owner's Demonstratives for Oral Argument
2/4/2022	Patent Owner's Certificate of Service for Demonstratives
2/4/2022	Petitioner's Updated Exhibit List
3/15/2022	Oral Hearing Transcript
5/2/2022	Final Written Decision

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

August 9, 2022

(Date)

THIS IS TO CERTIFY that the attached document is a list of the papers that comprise the record before the Patent Trial and Appeal Board (PTAB) for the *Inter Partes Review* proceeding identified below.

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2020-01716
Patent No. 10,702,194 B1
By authority of the

DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer



Prosecution History ~ IPR2020-01716

Date	Document
9/30/2020	Petition for Inter Partes Review
9/30/2020	Petitioner's Power of Attorney
10/20/2020	Patent Owner's Mandatory Notices
11/10/2020	Notice of Filing Date Accorded to Petition
1/22/2021	Petitioner's Exhibit List
2/10/2021	Patent Owner's Notice of Waiver of Preliminary Response
5/5/2021	Decision - Institution of Inter Partes Review
5/5/2021	Scheduling Order
5/19/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence Submitted Before Trial Institution
6/9/2021	Petitioner's Motion to Submit Supplemental Information
6/14/2021	Order - Motion to Submit Supplemental Information
6/21/2021	Petitioner's Submission of Supplemental Information
7/2/2021	Notice of Stipulation Modifying Due Dates 1-3
7/2/2021	Notice of Deposition - Kenny, Ph.D.
8/6/2021	Patent Owner's Response to Petition
8/6/2021	Patent Owner's Exhibit List
8/13/2021	Petitioner's Objections to Evidence
9/30/2021	Notice of Deposition - Madisetti, Ph.D.
11/1/2021	Petitioner's Reply to Patent Owner's Response
11/8/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence Served with Petitioner's Reply
11/17/2021	Notice of Deposition - Kenny, Ph.D.
12/13/2021	Patent Owner's Sur-Reply to Petitioner's Reply
12/13/2021	Patent Owner's Updated Exhibit List
12/14/2021	Petitioner's Updated Mandatory Notices
12/29/2021	Petitioner's Request for Oral Hearing
12/29/2021	Patent Owner's Request for Oral Argument
1/5/2022	Order - Setting Oral Argument
1/6/2022	Patent Owner's Authorized Corrected Sur-Reply to Reply
1/10/2022	Petitioner's Updated Mandatory Notices
1/21/2022	Patent Owner's Mandatory Notice Updating Counsel Information
2/4/2022	Patent Owner's Demonstratives for Oral Argument
2/4/2022	Patent Owner's Certificate of Service for Demonstratives
2/4/2022	Petitioner's Updated Exhibit List
3/15/2022	Oral Hearing Transcript
4/28/2022	Final Written Decision

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

August 9, 2022

(Date)

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APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

Case: IPR2020-01733
Patent No. 10,702,195 B1
By authority of the

DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Macia L. Fletcher

Certifying Officer



Prosecution History ~ IPR2020-01733

Date	Document
9/30/2020	Petition for Inter Partes Review
9/30/2020	Petitioner's Power of Attorney
10/20/2020	Patent Owner's Mandatory Notices
11/19/2020	Notice of Filing Date Accorded to Petition
1/22/2021	Petitioner's Exhibit List
2/19/2021	Patent Owner's Notice of Waiver of Preliminary Response
5/5/2021	Decision - Institution of Inter Partes Review
5/5/2021	Scheduling Order
5/19/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence Submitted Before Trial Institution
6/9/2021	Petitioner's Motion to Submit Supplemental Information
6/14/2021	Order - Motion to Submit Supplemental Information
6/21/2021	Petitioner's Submission of Supplemental Information
7/2/2021	Notice of Stipulation Modifying Due Dates 1-3
7/2/2021	Notice of Deposition - Kenny, Ph.D.
8/10/2021	Patent Owner's Response to Petition
8/10/2021	Patent Owner's Exhibit List
8/17/2021	Petitioner's Objections to Evidence
9/30/2021	Notice of Deposition - Madisetti, Ph.D.
11/8/2021	Petitioner's Reply to Patent Owner's Response
11/16/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence Served with Petitioner's Reply
12/14/2021	Petitioner's Updated Mandatory Notices
12/20/2021	Patent Owner's Sur-Reply to Petitioner's Reply
12/20/2021	Patent Owner's Updated Exhibit List
12/29/2021	Petitioner's Request for Oral Hearing
12/29/2021	Patent Owner's Request for Oral Argument
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1/10/2022	Petitioner's Updated Mandatory Notices
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2/4/2022	Patent Owner's Demonstratives for Oral Argument
2/4/2022	Patent Owner's Certificate of Service for Demonstratives
2/4/2022	Petitioner's Updated Exhibit List
3/15/2022	Oral Hearing Transcript
4/28/2022	Final Written Decision

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

August 9, 2022

(Date)

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APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

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Patent No. 10,709,366 B1
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Macia L. Fletcher

Certifying Officer



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Date	Document
9/30/2020	Petition for Inter Partes Review
9/30/2020	Petitioner's Power of Attorney
10/20/2020	Patent Owner's Mandatory Notices
11/19/2020	Notice of Filing Date Accorded to Petition
1/22/2021	Petitioner's Exhibit List
2/19/2021	Patent Owner's Notice of Waiver of Preliminary Response
5/12/2021	Decision - Institution of Inter Partes Review
5/12/2021	Scheduling Order
5/26/2021	Patent Owner's Objections to Petitioner's Evidence Submitted Before Trial Institution
6/9/2021	Petitioner's Motion to File Supplemental Information
6/14/2021	Order - Motion to Submit Supplemental Information
6/21/2021	Petitioner's Submission of Supplemental Information
7/2/2021	Notice of Stipulation Modifying Due Dates 1-3
7/2/2021	Notice of Deposition - Kenny, Ph.D.
8/12/2021	Patent Owner's Response to Petition
8/12/2021	Patent Owner's Exhibit List
8/19/2021	Petitioner's Objections to Evidence
9/30/2021	Notice of Deposition - Madisetti, Ph.D.
11/12/2021	Petitioner's Reply to Patent Owner's Response
11/19/2021	Patent Owner's Objections to Admissibility of Petitioner's Evidence Served with Petitioner's Reply
12/14/2021	Petitioner's Updated Mandatory Notices
12/22/2021	Patent Owner's Sur-Reply to Reply
12/22/2021	Patent Owner's Updated Exhibit List
12/29/2021	Petitioner's Request for Oral Hearing
12/29/2021	Patent Owner's Request for Oral Argument
1/5/2022	Order - Setting Oral Argument
1/10/2022	Petitioner's Updated Mandatory Notices
1/21/2022	Patent Owner's Mandatory Notice Updating Counsel Information
2/4/2022	Patent Owner's Demonstratives for Oral Argument
2/4/2022	Patent Owner's Certificate of Service for Demonstratives
2/4/2022	Petitioner's Updated Exhibit List
3/15/2022	Oral Hearing Transcript
5/4/2022	Final Written Decision

Trials@uspto.gov
571-272-7822

Paper 31
Entered: May 2, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01713
Patent 10,624,564 B1

Before JOSIAH C. COCKS, ROBERT L. KINDER, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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I. INTRODUCTION

A. Background

Apple Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–30 (“challenged claims”) of U.S. Patent No. 10,624,564 B1 (Ex. 1001, “the ’564 patent”). Paper 2 (“Pet.”). Masimo Corporation (“Patent Owner”) waived filing a Preliminary Response. Paper 6. We instituted an *inter partes* review of all challenged claims 1–30 on all asserted grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 7 (“Inst. Dec.”).

After institution, Patent Owner filed a Response (Paper 14, “PO Resp.”) to the Petition, Petitioner filed a Reply (Paper 18, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 21, “Sur-reply”). An oral hearing was held on February 9, 2022, and a transcript of the hearing is included in the record. Paper 30 (“Tr.”).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has met its burden of showing, by a preponderance of the evidence, that challenged claims 1–30 of the ’564 patent are unpatentable.

B. Related Proceedings

Masimo Corporation v. Apple Inc., Civil Action No. 8:20-cv-00048 (C.D. Cal.) (filed Jan. 9, 2020);

Apple Inc. v. Masimo Corporation, IPR2020-01520 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,258,265 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01521 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,292,628 B1);

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Apple Inc. v. Masimo Corporation, IPR2020-01523 (PTAB Sept. 9, 2020) (challenging claims of U.S. Patent No. 8,457,703 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01524 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,433,776 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01526 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 6,771,994 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01536 (PTAB Aug. 31, 2020) (challenging claims 1–29 of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01537 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01538 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01539 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01714 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01715 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01716 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,194 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01722 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01723 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01733 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,195 B1); and

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Apple Inc. v. Masimo Corporation, IPR2020-01737 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,709,366 B1).

Pet. 3; Paper 3, 1, 3–4.

Patent Owner further identifies certain pending patent applications, as well as other issued and abandoned applications, that claim priority to, or share a priority claim with, the '564 patent. Paper 3, 1–2.

C. The '564 Patent

The '564 patent is titled “Multi-Stream Data Collection System for Noninvasive Measurement of Blood Constituents,” and issued on April 21, 2020, from U.S. Patent Application No. 16/725,292, filed December 23, 2019. Ex. 1001, codes (21), (22), (45), (54). The '564 patent claims priority through a series of continuation and continuation-in-part applications to Provisional Application Nos. 61/086,060, 61/086,108, 61/086,063, and 61/086,057, each filed on August 4, 2008, as well as 61/091,732, filed on August 25, 2008, and 61/078,228 and 61/078,207, both filed on July 3, 2008. *Id.* at codes (60), (63).

The '564 patent discloses a two-part data collection system including a noninvasive sensor that communicates with a patient monitor. *Id.* at 2:47–51. The sensor includes a sensor housing, an optical source, and several photodetectors, and is used to measure a blood constituent or analyte, e.g., oxygen or glucose. *Id.* at 2:38–46, 3:4–6. The patient monitor includes a display and a network interface for communicating with a handheld computing device. *Id.* at 2:54–57.

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Figure 1 of the '564 patent is reproduced below.

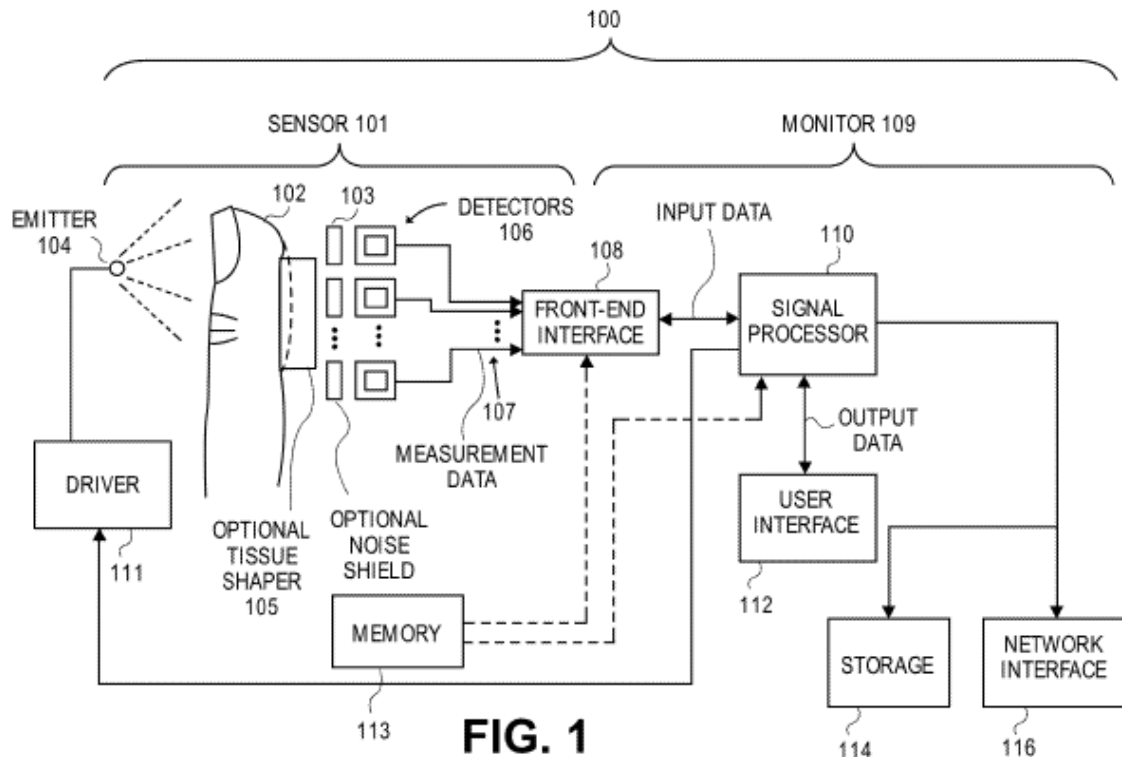


Figure 1 illustrates a block diagram of data collection system 100 including sensor 101 and monitor 109. *Id.* at 11:56–67. Sensor 101 includes emitter 104 and detectors 106. *Id.* at 12:1–5. Emitter 104 emits light that is attenuated or reflected by the patient's tissue at measurement site 102. *Id.* at 14:11–16. Detectors 106 capture and measure the light attenuated or reflected from the tissue. *Id.* In response to the measured light, detectors 106 output detector signal 107 to monitor 109 through front-end interface 108. *Id.* at 14:16–19, 36–42. Sensor 101 also may include tissue shaper 105, which may be in the form of a convex surface that: (1) reduces the thickness of the patient's measurement site; and (2) provides more surface area from which light can be detected. *Id.* at 11:7–23.

Monitor 109 includes signal processor 110 and user interface 112. *Id.* at 15:27–29. “[S]ignal processor 110 includes processing logic that

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determines measurements for desired analytes . . . based on the signals received from the detectors 106.” *Id.* at 15:32–35. User interface 112 presents the measurements to a user on a display, e.g., a touch-screen display. *Id.* at 15:57–61. In response to user input or device orientation, user interface 112 can “reorient its display indicia.” *Id.* at 15:63–67. The monitor may be connected to storage device 114 and network interface 116. *Id.* at 16:4–22. In some embodiments, the monitor, including the display, is attached to the patient by a strap. *Id.* at 17:56–59, 18:16–19.

The ’564 patent describes various examples of sensor devices. Figures 14D and 14F, reproduced below, illustrate sensor devices.

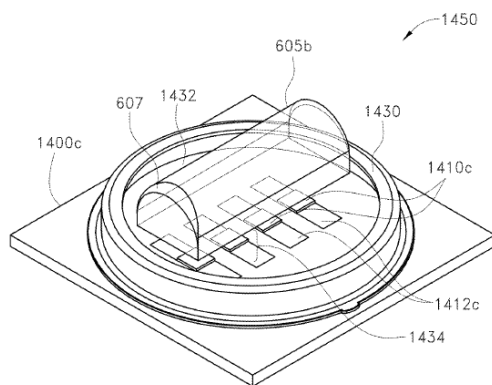


FIG. 14D

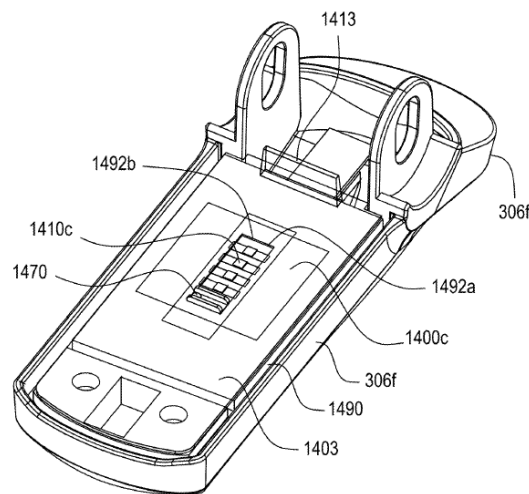


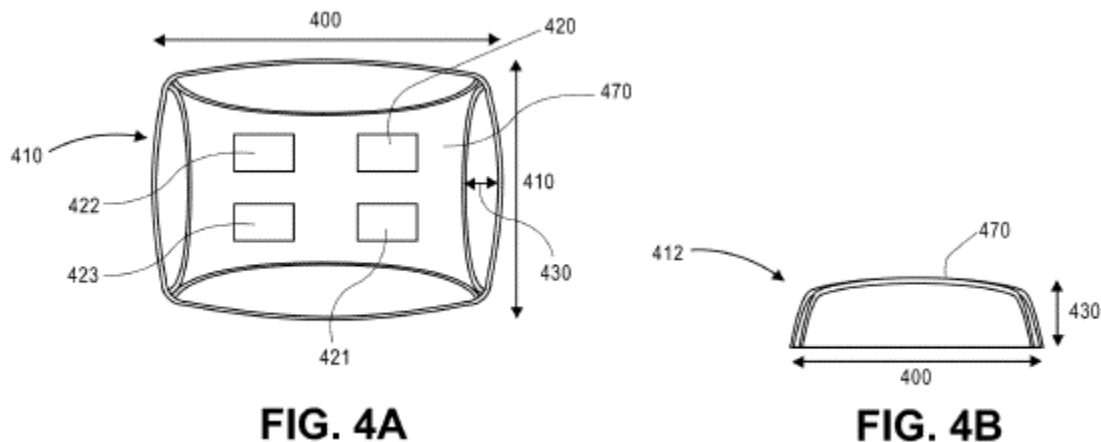
FIG. 14F

Figure 14D illustrates a detector submount and Figure 14F illustrates portions of a detector shell. *Id.* at 6:54–57. As shown in Figure 14D, multiple detectors 1410c are located within housing 1430 and under transparent cover 1432, on which protrusion 605b is disposed. *Id.* at 36:40–47. Figure 14F illustrates detector shell 306f including detectors 1410c on substrate 1400c. *Id.* at 37:20–21. In some embodiments, the detector shell includes walls to separate individual photodiode arrays and to “prevent or

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reduce mixing of light signals.” *Id.* at 22:46–53. Substrate 1400c is enclosed by shielding enclosure 1490 and noise shield 1403, which include window 1492a and window 1492b, respectively, placed above detectors 1410c. *Id.* at 22:20–36.

Figures 4A and 4B, reproduced below, illustrate an alternative example of a tissue contact area of a sensor device.



Figures 4A and 4B illustrate arrangements of protrusion 405 including measurement site contact area 470. *Id.* at 23:30–36. “[M]easurement site contact area 470 can include a surface that molds body tissue of a measurement site.” *Id.* “For example, the measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site.” *Id.* at 23:53–55. The measurement site contact area includes windows 420–423 that “mimic or approximately mimic a configuration of, or even house, a plurality of detectors.” *Id.* at 23:61–24:8.

D. Illustrative Claim

Of the challenged claims, claim 1 is independent. Claim 1 is illustrative and is reproduced below.

1. [pre] A user-worn physiological measurement device comprising:

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[a] one or more emitters configured to emit light into tissue of a user;

[b] at least four detectors arranged on a substrate;

[c] a cover comprising a protruding convex surface, wherein the protruding convex surface extends over all of the at least four detectors arranged on the substrate, wherein at least a portion of the protruding convex surface is rigid;

[d] one or more processors configured to: receive one or more signals from at least one of the at least four detectors, the one or more signals responsive to at least a physiological parameter of the user; and process the one or more signals to determine measurements of the physiological parameter;

[e] a network interface configured to communicate with a mobile phone;

[f] a touch-screen display configured to provide a user interface,

[g] wherein: the user interface is configured to display indicia responsive to the measurements of the physiological parameter, and

[h] an orientation of the user interface is configurable responsive to a user input;

[i] a wall that surrounds at least the at least four detectors, wherein the wall operably connects to the substrate and the cover;

[j] a storage device configured to at least temporarily store at least the measurements of the physiological parameter; and

[k] a strap configured to position the physiological measurement device on the user.

Ex. 1001, 44:63–45:29 (bracketed lettering [pre]–[k] added).

E. Applied References

Petitioner relies upon the following references:

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Sherman et al., U.S. Patent No. 4,941,236, filed July 6, 1989, issued July 17, 1990 (Ex. 1013, “Sherman”);

Ali et al., U.S. Patent No. 6,584,336 B1, filed March 1, 2000, issued June 24, 2003 (Ex. 1019, “Ali”);

Rantala et al., U.S. Patent No. 6,912,413 B2, filed September 12, 2003, issued June 28, 2005 (Ex. 1022, “Rantala”);

Ohsaki et al., U.S. Patent Application Publication No. 2001/0056243 A1, filed May 11, 2001, published December 27, 2001 (Ex. 1009, “Ohsaki”);

Aizawa, U.S. Patent Application Publication No. 2002/0188210 A1, filed May 23, 2002, published December 12, 2002 (Ex. 1006, “Aizawa”); and

Goldsmith et al., U.S. Patent Application Publication No. 2007/0093786 A1, filed July 31, 2006, published April 26, 2007 (Ex. 1011, “Goldsmith”).

Pet. 10.

Petitioner also submits, *inter alia*, a Declaration of Dr. Thomas W. Kenny, Ph.D. (Ex. 1003) and a Second Declaration of Dr. Kenny (Ex. 1050). Patent Owner submits, *inter alia*, the Declaration of Dr. Vijay K. Madiseti (Ex. 2004). The parties also provide deposition testimony from Dr. Kenny and Dr. Madiseti, including from this proceeding and others. Exs. 1053–1056, 2006–2009, 2027.

F. Asserted Grounds of Unpatentability

We instituted an *inter partes* review based on the following grounds. Inst. Dec. 10–11, 42.

Claim(s) Challenged	35 U.S.C. §	References/Basis
1–10, 13–30	103	Aizawa, Ohsaki, Goldsmith
11	103	Aizawa, Ohsaki, Goldsmith, Sherman

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Claim(s) Challenged	35 U.S.C. §	References/Basis
12	103	Aizawa, Ohsaki, Goldsmith, Rantala
1–10, 13–30	103	Aizawa, Ohsaki, Goldsmith, Ali
11	103	Aizawa, Ohsaki, Goldsmith, Ali, Sherman
12	103	Aizawa, Ohsaki, Goldsmith, Ali, Rantala

II. DISCUSSION

A. Claim Construction

For petitions filed on or after November 13, 2018, a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b) (2020). Accordingly, we construe the claims according to the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Based on our analysis of Petitioner’s challenges presented, we find that one claim term requires express construction.

Petitioner raises the issue of the proper scope of the claim term “processor” from claim 1 to a person of ordinary skill in the art. Pet. 51. Petitioner submits “[t]he ’564 patent does not define ‘processor,’” but argues that a person of ordinary skill in the art would understand the term to mean “part of a computer system that operates on data,” consistent with the definition provided in Merriam-Webster’s Collegiate Dictionary.¹ *Id.*; Ex. 1012, 5.

¹ Petitioner adds page numbers 1–6 to Exhibit 1012. We refer to the added page numbers when citing to Exhibit 1012 in this Decision.

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In our Institution Decision, we observed that the claim language provides an understanding of the functions of the claimed one or more processors, which are “configured to:” “receive one or more signals” and “process the one or more signals to determine measurements of the physiological parameter.” Inst. Dec. 11–12 (quoting Ex. 1001, 45:6–12). We noted that “[t]he Specification describes several distinct processors, but it also describes a ‘signal processor’ as the device used for processing signals.” *Id.* at 12; *see, e.g.*, Ex. 1001, 9:50–55, 14:36–42, 15:27–56, 33:36–47.

Patent Owner does not object to our initial claim construction, and submits that claim terms should be given their ordinary and customary meaning, consistent with the Specification. PO Resp. 7.

Based on the final record, we maintain our initial interpretation of the term “processor” as meaning “part of a computer system that operates on data.” *See* Ex. 1012, 5. This definition is consistent with the general operation of the signal processor in the ’564 patent, where the signal processor is described to include “processing logic that determines measurements . . . based on the signals received from the detectors.” Ex. 1001, 15:31–35; 15:35–39 (“signal processor 110 can be implemented using one or more microprocessors or subprocessors . . . digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same”).

Based on our analysis of the issues in dispute, we conclude that no further claim terms require express construction. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

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B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness.² *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

² The parties have not presented objective evidence of non-obviousness.

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We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner identifies the appropriate level of skill in the art as that possessed by a person having “a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information.” Pet. 8 (citing Ex. 1003 ¶¶ 21–22). “Additional education in a relevant field or industry experience may compensate for one of the other aspects of the . . . characteristics stated above.” *Id.*

Patent Owner makes several observations regarding Petitioner’s identified level of skill in the art but, “[f]or this proceeding, [Patent Owner] nonetheless applies Petitioner’s asserted level of skill.” PO Resp. 7–8.

We adopt Petitioner’s assessment as set forth above, which appears consistent with the level of skill reflected in the Specification and prior art.

*D. Obviousness over the Combined Teachings of
Aizawa, Ohsaki, and Goldsmith*

Petitioner contends that claims 1–10 and 13–30 of the ’564 patent would have been obvious over the combined teachings of Aizawa, Ohsaki, and Goldsmith. Pet. 10–91; *see also* Pet. Reply 7–37. Patent Owner disagrees. PO Resp. 9–51; *see also* Sur-reply 1–27.

Based on our review of the parties’ arguments and the cited evidence of record, we determine that Petitioner has met its burden of showing by a preponderance of the evidence that claims 1–10 and 13–30 are unpatentable.

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1. Overview of Aizawa (Ex. 1006)

Aizawa is a U.S. patent application publication titled “Pulse Wave Sensor and Pulse Rate Detector,” and discloses a pulse wave sensor that detects light output from a light emitting diode and reflected from a patient’s artery. Ex. 1006, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

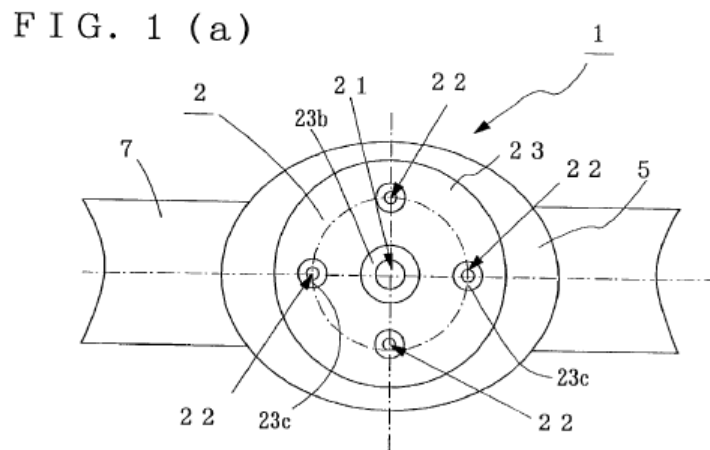


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode (“LED”) 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses that, “to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased.” *Id.* ¶ 32, Fig. 4(a). “The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22.” *Id.* ¶ 33.

Figure 1(b) of Aizawa is reproduced below.

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F I G . 1 (b)

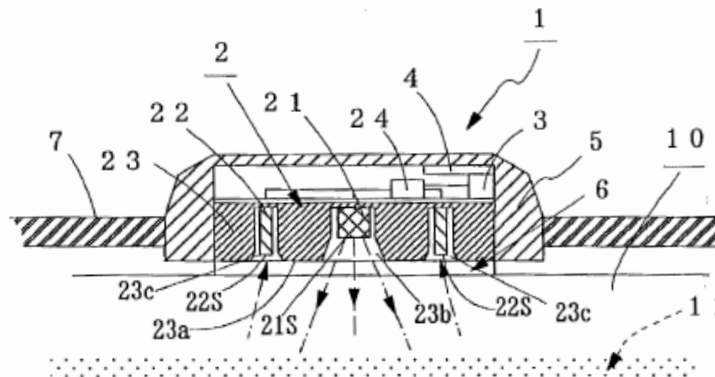


Figure 1(b) is a sectional view of the pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(b), pulse wave sensor 2 includes drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of photodetectors 22. *Id.* Arithmetic circuit 3 computes a pulse rate from the detected pulse wave and transmitter 4 transmits the pulse rate data to an “unshown display.” *Id.* The pulse rate detector further includes outer casing 5 for storing pulse wave sensor 2, acrylic transparent plate 6 mounted to detection face 23a of holder 23, and attachment belt 7. *Id.*

Aizawa discloses that LED 21 and photodetectors 22 “are stored in cavities 23b and 23c formed in the detection face 23a” of the pulse wave sensor. *Id.* ¶ 24. Detection face 23a “is a contact side between the holder 23 and a wrist 10, respectively, at positions where the light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back from the above detection face 23a.” *Id.* Aizawa discloses that “a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 . . . in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side).” *Id.* ¶ 26. Furthermore, “the above belt 7 is fastened such that the acrylic

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transparent plate 6 becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved.”

Id. ¶¶ 26, 34.

2. Overview of Ohsaki (Ex. 1009)

Ohsaki is a U.S. patent application publication titled “Wristwatch-type Human Pulse Wave Sensor Attached on Back Side of User’s Wrist,” and discloses “an optical sensor for detecting [a] pulse wave of a human body.” Ex. 1009, code (54), ¶ 3. Figure 1 of Ohsaki is reproduced below.

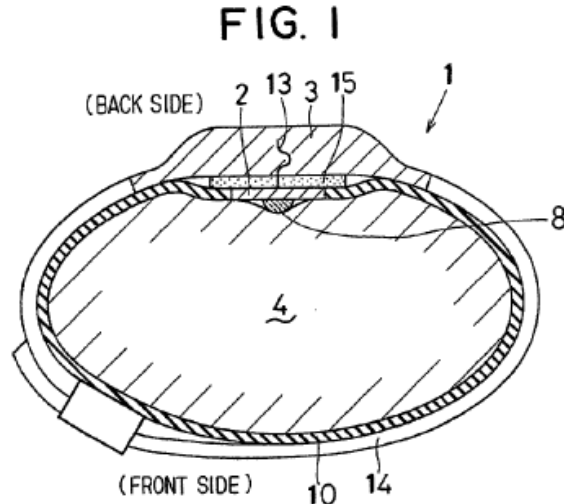


Figure 1 illustrates a cross-sectional view of pulse wave sensor 1 attached on the back side of user’s wrist 4. *Id.* ¶¶ 12, 16. Pulse wave sensor 1 includes detecting element 2 and sensor body 3. *Id.* ¶ 16.

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Figure 2 of Ohsaki, reproduced below, illustrates further detail of detecting element 2.

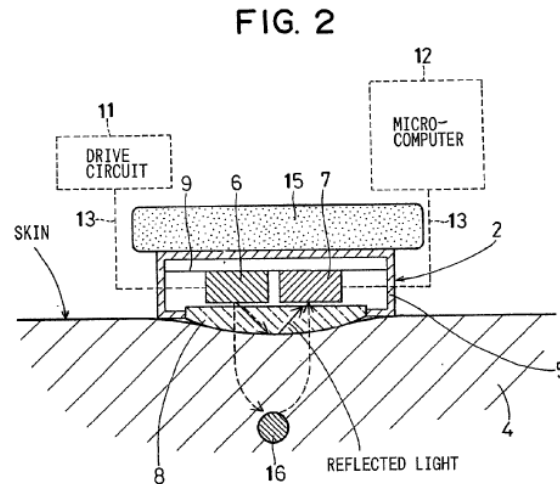


Figure 2 illustrates a mechanism for detecting a pulse wave. *Id.* ¶ 13. Detecting element 2 includes package 5, light emitting element 6, light receiving element 7, and translucent board 8. *Id.* ¶ 17. Light emitting element 6 and light receiving element 7 are arranged on circuit board 9 inside package 5. *Id.* ¶¶ 17, 19.

“[T]ranslucent board 8 is a glass board which is transparent to light, and attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8.” *Id.* ¶ 17. “[T]he convex surface of the translucent board 8 is in intimate contact with the surface of the user’s skin,” preventing detecting element 2 from slipping off the detecting position of the user’s wrist. *Id.* ¶ 25. By preventing the detecting element from moving, the convex surface suppresses “variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user’s skin.” *Id.* Additionally, the convex surface prevents penetration by “noise such as disturbance light from the outside.” *Id.*

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Sensor body 3 is connected to detecting element 2 by signal line 13. *Id.* ¶ 20. Signal line 13 connects detecting element 2 to drive circuit 11, microcomputer 12, and a monitor display (not shown). *Id.* Drive circuit 11 drives light emitting element 6 to emit light toward wrist 4. *Id.* Detecting element 2 receives reflected light which is used by microcomputer 12 to calculate pulse rate. *Id.* “The monitor display shows the calculated pulse rate.” *Id.*

3. Overview of Goldsmith (Ex. 1011)

Goldsmith is a U.S. patent application publication titled “Watch Controller for a Medical Device,” and discloses a watch controller device that communicates with an infusion device to “provid[e] convenient monitoring and control of the infusion pump device.” Ex. 1011, codes (54), (57).

Goldsmith’s Figure 9A and 9B are reproduced below.

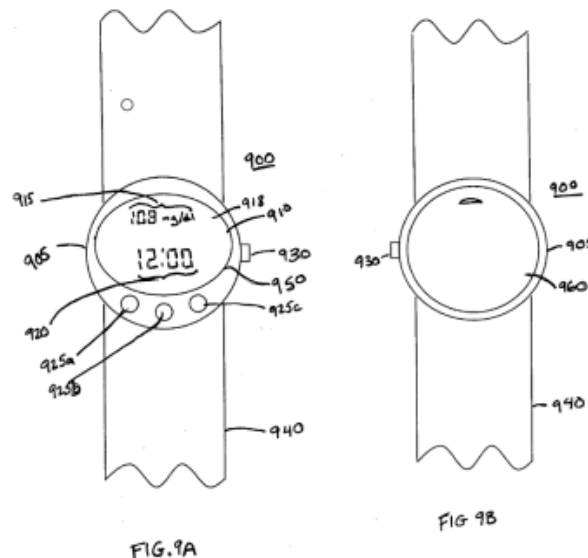


Figure 9A and Figure 9B are respective front and rear views of a combined watch and controller device. *Id.* ¶¶ 30–31. As shown in Figure 9A, watch

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controller 900 includes housing 905, transparent member 950, display 910, input devices 925a–c, scroll wheel 930, and wrist band 940. *Id.* ¶¶ 85–86. Figure 9B shows rear-side cover 960, and a rear view of housing 905, scroll wheel 930, and wrist band 940. *Id.*

Goldsmith discloses the watch controller may interact with one or more devices, such as infusion pumps or analyte monitors. *Id.* ¶ 85; *see also id.* ¶ 88 (“The analyte sensing device 1060 may be adapted to receive data from a sensor, such as a transcutaneous sensor.”). Display 910 “may display at least a portion of whatever information and/or graph is being displayed on the infusion device display or on the analyte monitor display,” such as, e.g., levels of glucose. *Id.* ¶ 86. The display is customizable in a variety of configurations including user-customizable backgrounds, languages, sounds, font (including font size), and wall papers. *Id.* ¶¶ 102, 104. Additionally, the watch controller may communicate with a remote station, e.g., a computer, to allow data downloading. *Id.* ¶ 89 (including wireless). The remote station may also include a cellular telephone to be “used as a conduit for remote monitoring and programming.” *Id.*

4. Independent Claim 1

Petitioner contends that claim 1 would have been obvious over the combined teachings of Aizawa, Ohsaki, and Goldsmith. Pet. 10–63. Below, we set forth how the combination of prior art references teaches or suggests the claim limitations that are not disputed by the parties. For those limitations and reasons for combining the references that are disputed, we examine each of the parties’ contentions and then provide our analysis.

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i. “[pre] A user-worn physiological measurement device comprising”

The cited evidence supports Petitioner’s undisputed contention that Aizawa satisfies the subject matter of the preamble.³ Pet. 41–42; *see, e.g.*, Ex. 1006 ¶ 26, code (57) (“a subject carries the above pulse rate detector 1 on the inner side of his/her wrist”), Fig. 2 (depicting a user wearing a pulse wave sensor on the inner side of his/her wrist); *see also* Ex. 1003 ¶ 98.⁴

ii. “[a] one or more emitters configured to emit light into tissue of a user”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses an emitter, LED 21, that emits light into a user’s tissue. Pet. 42–43; *see, e.g.*, Ex. 1006 ¶ 23 (“LED 21 . . . for emitting light having a wavelength of a near infrared range”), ¶ 27 (explaining that light is emitted toward the wrist), Fig. 1(b) (depicting LED 21 facing user wrist 10), Fig. 2 (depicting a pulse wave sensor worn on a user’s wrist).

iii. “[b] at least four detectors arranged on a substrate;”

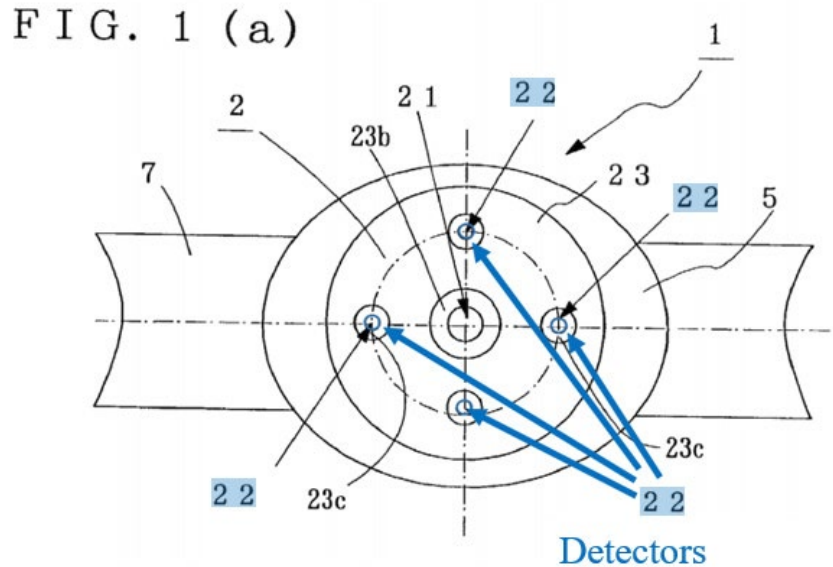
The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses at least four detectors. Pet. 23–25, 44–46; *see, e.g.*,

³ Whether the preamble is limiting need not be resolved because Petitioner shows sufficiently that the preamble’s subject matter is satisfied by the art.

⁴ Petitioner further contends that the subject matter of the preamble is taught by the combination of Aizawa, Ohsaki, and Goldsmith. Pet. 41–42 (arguing that it would have been obvious to incorporate the pulse wave sensor of Aizawa (as modified by Ohsaki) into the wrist-worn watch controller device in Figures 9A and 9B of Goldsmith, to realize a user-worn physiological measurement device). Because Figure 2 of Aizawa teaches a user-worn physiological measurement device, further analysis of the combination of Aizawa, Ohsaki, and Goldsmith is not necessary for the preamble.

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Ex. 1006 ¶¶ 9, 23 (“four phototransistors 22”), Figs. 1(a)–1(b); Ex. 1003 ¶¶ 43–45, 64–67. Petitioner contends that pulse wave sensor depicted in Figure 1(a) of Aizawa, reproduced below, discloses four photodetectors 22. Pet. 44; *see, e.g.*, Ex. 1006 ¶ 27 (“[F]our photodetectors 22 are disposed around the light emitting diode 21.”).

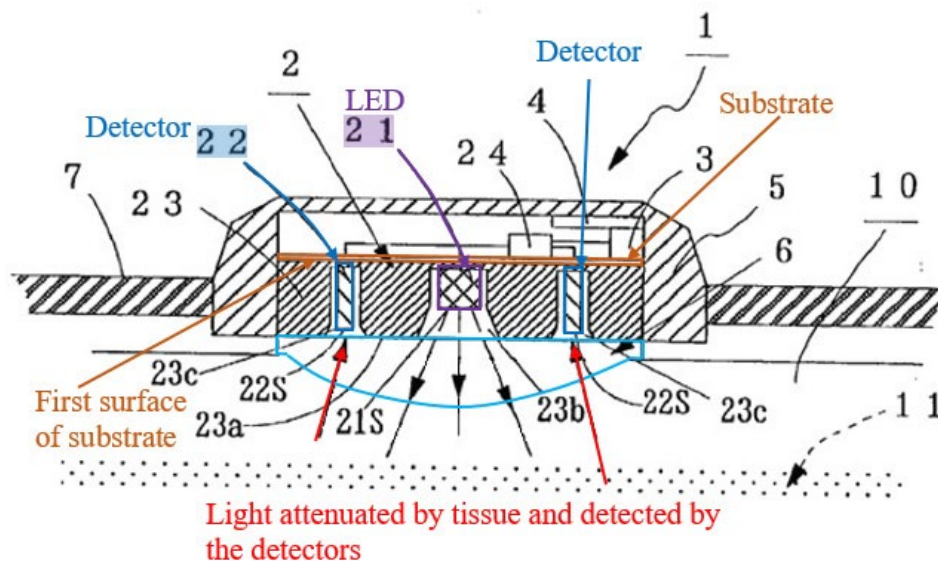


Petitioner’s Annotated Figure 1(a) of Aizawa depicts four photodetectors 22, identified by blue arrows and blue shading.

Relying on a cross-section view of Figure 1(b) of the pulse wave detector of Aizawa, Petitioner further contends photodetectors 22 are secured on a substrate illustrated in Petitioner’s annotated Figure 1(b). Pet. 24, 45. Petitioner’s annotated Figure 1(b) of Aizawa is reproduced below.

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FIG. 1 (b)



Annotated Figure 1(b) depicts a structure, identified by Petitioner with brown highlight and the added label “Substrate,” arranged in proximity to photodetectors 22. Pet. 45. Petitioner concedes that Aizawa “does not label or describe” a substrate, but contends a person of ordinary skill in the art (“POSITA”) would have understood that “Aizawa’s photodetectors are secured to the [physiological measure device] . . . through such a substrate” depicted in annotated Figure 1(b). Pet. 24. Dr. Thomas W. Kenny testifies that “[a] POSITA would have understood that the substrate provides physical support and electrical connectivity and is connected to the holder 23.” Ex. 1003 ¶ 71; *see also* Pet. 24 (citing to testimony of Dr. Kenny). On the current record, Petitioner has sufficiently shown that the structure identified in annotated Figure 1(b) of Aizawa is a substrate, and that photodetectors 22 are arranged on the substrate.

Petitioner further contends that if Aizawa is found not to disclose a substrate, then Ohsaki teaches this feature. Pet. 25. Similar to the device of Aizawa, Ohsaki teaches a pulse wave sensor comprising a light emitting

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element 6 (e.g., a LED) and a light receiving element (e.g., a photodetector). Ex. 1009 ¶ 17. “The light emitting element 6 and light receiving element 7 are . . . arranged on the circuit board 9.” *Id.* Relying on the testimony of Dr. Kenny, Petitioner contends a POSITA would have modified the pulse wave sensor of Aizawa to include a substrate, such as circuit board 9 of Ohsaki, to secure the photodetectors of Aizawa and enable the detectors to send signals to other elements in the device. Pet. 25 (citing Ex. 1003 ¶¶ 72–73; Ex. 1006 ¶¶ 2–5, 8–16, 23, 27–29, 32–33, Figs. 1, 2, 3, 4(a); Ex. 1009 ¶ 17, Fig. 2).

The cited evidence, including the unrebutted testimony of Dr. Kenny, sufficiently supports Petitioner’s stated reasoning.

iv. “[c] a cover comprising a protruding convex surface, wherein the protruding convex surface extends over all of the at least four detectors arranged on the substrate, wherein at least a portion of the protruding convex surface is rigid”

Petitioner’s Undisputed Contentions

Petitioner contends that Aizawa discloses a cover, i.e., a “transparent plate positioned between the photodetectors and the wrist.” Pet. 12 (citing Ex. 1006 ¶ 34). Patent Owner does not dispute this contention, and we agree with Petitioner. Aizawa discloses that “acrylic transparent plate 6 is provided on the detection face 23a of the holder 23 to improve adhesion to the wrist 10.” Ex. 1006 ¶ 34, Fig. 1(b) (depicting transparent plate 6 between sensor 2 and wrist 10).

Petitioner also contends that Ohsaki teaches a wrist-worn sensor that includes a “translucent board” having a convex surface that contacts the user’s skin. Pet. 15, 21. Patent Owner does not dispute this contention, and

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we agree with Petitioner. Ohsaki discloses that sensor 1 includes detecting element 2 and sensor body 3, and is “worn on the back side of the user’s wrist.” Ex. 1009 ¶ 16. Ohsaki discloses that detecting element 2 includes package 5 and “translucent board 8[,which] is a glass board which is transparent to light, and [is] attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8.” *Id.* ¶ 17. As seen in Ohsaki’s Figure 2, translucent board 8 has a single protruding convex surface, which is placed between a user’s tissue and a light receiving element (e.g., photodetector) 7 when the sensor is worn. *Id.* at Fig. 2. As also seen in Figure 2, the board 8 is operably connected to the walls of sensor package 5. *Id.* ¶ 17 (“The translucent board 8 is . . . attached to the opening of the package 5.”), Fig. 2.

Claim 1 further requires that “at least a portion of the protruding convex surface is rigid.” Petitioner contends that Ohsaki’s Figure 2 depicts the user’s tissue in intimate contact with the convex surface of the cover and the cover is sufficiently rigid to cause the skin to deform. Pet. 15, 48 (The “convex surface . . . causes the user’s skin to deform . . . due to the rigidity of the convex surface.”). Patent Owner does not dispute this contention, and we agree with Petitioner. Ohsaki’s Figure 2 depicts the user’s tissue 4 deforming and conforming to the shape of the protruding convex surface when the sensor is worn by the user. Ex. 1009 ¶ 17 (“The translucent board 8 is a glass board.”), Fig. 2.

Petitioner’s Disputed Contentions

Petitioner further contends that a person of ordinary skill in the art “would have found it obvious to modify Aizawa’s sensor to include a cover having a protruding convex surface,” so as to [1] improve adhesion between

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the user’s wrist and the sensor’s surface, [2] improve detection efficiency, and [3] protect the elements within sensor housing. Pet. 20–23 (citing, e.g., Ex. 1003 ¶¶ 67–70; Ex. 1009 ¶ 25). Petitioner contends that Ohsaki’s convex surface is in “intimate contact” with the user’s skin, which prevents slippage of the sensor and increases signal strength because “variation of the amount of the reflected light . . . that reaches the light receiving element 7 is suppressed” and because “the pulse wave can be detected without being affected by the movement of the user’s wrist 4,” as compared to a sensor with a flat surface. *Id.* at 21–22 (citing, e.g., Ex. 1003 ¶ 68; quoting Ex. 1009 ¶¶ 15, 17, 25, Figs. 1, 2, 4A, 4B). Accordingly, Petitioner contends that a person of ordinary skill in the art would have modified Aizawa’s sensor to include a cover with a protruding convex surface, as taught by Ohsaki, that is “between a surface of the sensor and the user’s wrist.” Pet. 20–22 (citing, e.g., Ex. 1003 ¶¶ 67–70).

Petitioner contends this modification would have been “nothing more than the use of a known technique to improve similar devices in the same way,” i.e., “when Ohsaki’s PMD is worn ‘the convex surface of the translucent board . . . is in intimate contact with the . . . user’s skin’; this contact prevents slippage, which increases the strength of the obtainable signals.” Pet. 20–21 (citing Ex. 1003 ¶¶ 67–68).

To illustrate its proposed modification, Petitioner includes two annotated versions of Aizawa’s Figure 1(b), both of which are reproduced below. Pet. 19–23 (citing Ex. 1003 ¶¶ 66–70).

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FIG. 1 (b)

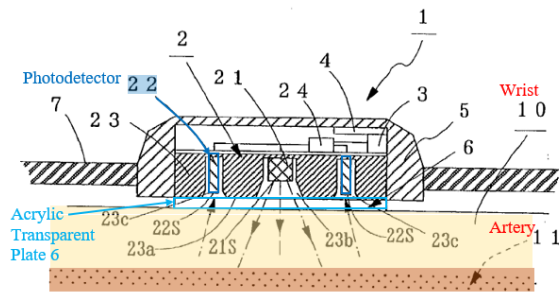
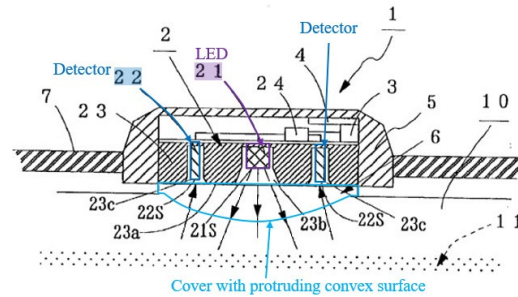


FIG. 1 (b)



Petitioner’s annotated figure on the left depicts Aizawa’s sensor, modified to include a flat “acrylic transparent plate” (illustrated with blue outline); Petitioner’s annotated figure on the right depicts Aizawa’s sensor, modified to include a “cover with protruding convex surface” (illustrated with blue outline).

Patent Owner’s Arguments

Patent Owner argues that a person of ordinary skill in the art would not have been motivated to modify Aizawa’s sensor to include Ohsaki’s convex cover. PO Resp. 16–46;⁵ Sur-reply 3–25.

First, Patent Owner argues “Ohsaki’s rectangular board would be incompatible with Aizawa’s circular sensor arrangement” and that the proposed modification “eliminates the longitudinal shape that Ohsaki specifically identifies as important for the benefit of reducing slipping.” PO Resp. 16–18 (emphases omitted). This argument is premised on Patent

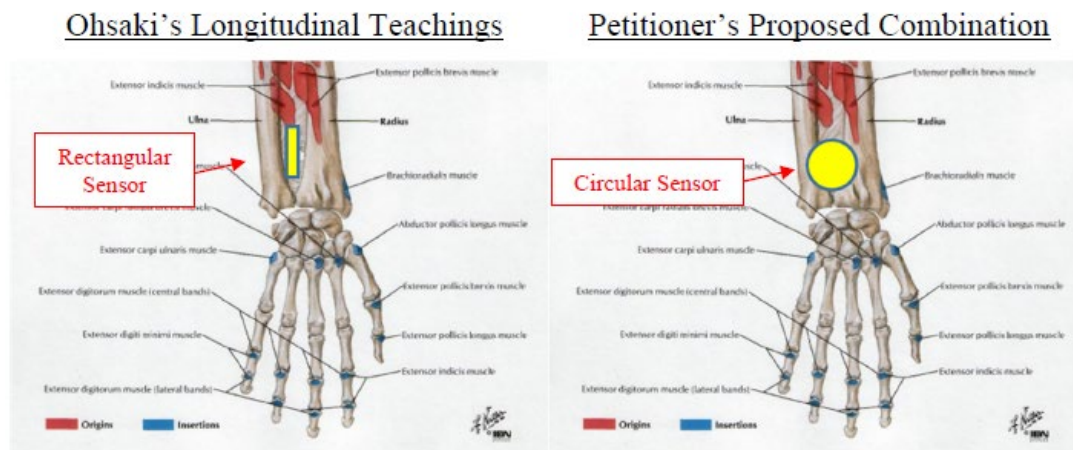
⁵ Patent Owner further argues, “[t]o the extent Petitioner contends a [person of ordinary skill in the art] would use Ohsaki’s rectangular board on Aizawa’s circular sensor . . . , that argument is unsupported and incorrect.” PO Resp. 23 (emphasis omitted). We do not read the Petition as making such a contention. We understand Petitioner to propose, in essence, changing Aizawa’s circular *flat* cover into a circular *convex* cover. See, e.g., Pet. 22–23.

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Owner's contention that Ohsaki's convex cover must be rectangular, with the cover's long direction aligned with the length of the user's forearm, to avoid interacting with bones in the wrist and forearm. *Id.* at 18–23 (citing, e.g., Ex. 2004 ¶¶ 48–55; Ex. 1009 ¶¶ 6, 19, 23–25); *see also* Sur-reply 3–11. According to Patent Owner, Ohsaki teaches that “aligning the sensor's longitudinal direction with the circumferential direction of the user's arm undesirably results in ‘a tendency [for Ohsaki's sensor] to slip off.’” PO Resp. 19 (emphasis omitted) (alteration in original) (citing Ex. 1009 ¶ 19).

Thus, Patent Owner contends that Petitioner's proposed modification would “chang[e] Ohsaki's rectangular board into a circular shape,” which “would eliminate the advantages discussed above” because it “cannot be placed in any longitudinal direction and thus [could not] coincide with the longitudinal direction of the user's wrist.” *Id.* at 20–21 (emphases omitted) (citing Ex. 2004 ¶¶ 50–51). Patent Owner presents annotated Figures depicting what it contends is Ohsaki's disclosed sensor placement as compared to that of the proposed modification, reproduced below.



Patent Owner's annotated Figure on the left depicts a rectangular sensor placed between a user's radius and ulna, while Patent Owner's annotated

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Figure on the right depicts a circular sensor placed across a user's radius and ulna. Based on these annotations, Patent Owner argues that the proposed "circular shape would press on the user's arm in all directions and thus [would not] avoid [the] undesirable interaction with the user's bone structure," such that a skilled artisan "would have understood that any such change would eliminate Ohsaki's benefit of preventing slipping." PO Resp. 21–23 (citing, e.g., Ex. 2004 ¶¶ 48–55).

Patent Owner additionally argues that "changing Aizawa's circular sensor to accommodate Ohsaki's longitudinal structure would result in less consistent measurements" and would "disrupt Aizawa's circular symmetry." *Id.* at 2. This argument is premised on Patent Owner's contention that Ohsaki's convex cover must be rectangular. *Id.* at 23 (citing Ex. 2004 ¶ 57). According to Patent Owner, "placing Ohsaki's rectangular board onto Aizawa's circular sensor would result in undesirable asymmetrical pressure and inconsistent contact at the peripheral edge where Aizawa's detectors are located," which would "create air gaps over some of Aizawa's peripherally arrayed detectors, but not others, which could result in degraded optical signals." *Id.* at 24–25 (emphasis omitted) (citing Ex. 2004 ¶¶ 58–59). Thus, Patent Owner argues that a person of ordinary skill in the art "would not have been motivated to use Ohsaki's rectangular board with Aizawa's circular sensor." *Id.* at 25 (citing Ex. 2004 ¶¶ 58–59).

Second, Patent Owner argues that Ohsaki requires its sensor be placed on the back of the user's wrist to achieve any benefits, but that such a location would have been unsuitable for Aizawa's sensor. PO Resp. 25–26. Specifically, Patent Owner argues that Aizawa's sensor must be worn on the palm side of the wrist, close to radial and ulnar arteries, which is the side

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opposite from where Ohsaki's sensor is worn. *Id.* at 26–32 (citing, e.g., Ex. 1006 ¶¶ 2, 7, 9, 26, 27, 36; Ex. 2004 ¶¶ 60–67). According to Patent Owner, Ohsaki teaches that the sensor's convex surface has a tendency to slip when placed on the palm side of the wrist, i.e., in the location taught by Aizawa. *Id.* at 32–35 (citing, e.g., Ex. 1009 ¶¶ 19, 23–24; Ex. 2004 ¶¶ 68–80). Thus, Patent Owner argues that a person of ordinary skill in the art “would not have been motivated to use Ohsaki's longitudinal board—designed to be worn on the back side of a user's wrist—with Aizawa's palm-side sensor.” *Id.* at 35 (emphases omitted). Similarly, Patent Owner argues that Aizawa teaches away from the proposed modification because Aizawa teaches that its flat acrylic plate improves adhesion on the palm side of the wrist, while Ohsaki teaches that its convex board “has a tendency to slip” on the palm side of the wrist. *Id.* at 35–38 (citing, e.g., Ex. 2004 ¶¶ 75–78).

Third, Patent Owner argues that a person of ordinary skill in the art would not have placed Ohsaki's convex cover over Aizawa's peripheral detectors because the convex cover would condense light toward the center and away from Aizawa's detectors, which would decrease optical signal strength. PO Resp. 38–44 (citing, e.g., Ex. 2004 ¶¶ 79–88). Patent Owner also contends that Petitioner and Dr. Kenny admitted as much in a related proceeding. *Id.* at 39–40 (citing, e.g., Ex. 2019, 45; Ex. 2020, 69–70). Patent Owner also relies on Figure 14B of the '564 patent to support its position. *Id.* at 40 (citing Ex. 1001, 36:12–15, 36:23–25). In light of the foregoing, Patent Owner argues that a person of ordinary skill in the art would have understood that the proposed modification would have decreased signal strength by directing light away from Aizawa's peripheral detectors. *Id.* at 43.

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Fourth and finally, Patent Owner argues that a person of ordinary skill in the art “would have understood that Aizawa’s flat plate would provide better protection than a convex surface” because it “would be less prone to scratches.” *Id.* at 44–46 (citing Ex. 1008 ¶ 106; Ex. 2004 ¶ 90) (emphasis omitted).

Petitioner’s Reply

Concerning Patent Owner’s first and second arguments, Petitioner responds that Ohsaki does not disclose the shape of its protrusion, other than its convexity as shown in Figures 1 and 2, nor does Ohsaki require a rectangular shape or placement on the back of the wrist in order to achieve the disclosed benefits. Pet. Reply 7–20 (citing, e.g., Ex. 1050 ¶¶ 7–30). Moreover, Petitioner asserts that “even if Ohsaki’s translucent board 8 were [somehow] understood to be rectangular, obviousness does not require ‘bodily incorporation’ of features from one reference into another”; rather, a person of ordinary skill in the art “would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits” taught by Ohsaki. *Id.* at 15–16 (citing, e.g., Ex. 1050 ¶ 23). Similarly, regarding the location of the sensor, Petitioner asserts,

[E]ven assuming for the sake of argument that a [person of ordinary skill in the art] would have understood Aizawa’s sensor as being limited to placement on the backside of the wrist, and would have understood Ohsaki’s sensor’s “tendency to slip” when arranged on the front side as informing consideration of Ohsaki’s teachings with respect to Aizawa, that would have further motivated the [person of ordinary skill in the art] to implement a light permeable convex cover in Aizawa’s sensor, to improve detection efficiency of that sensor when placed on the palm side.

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Id. at 18 (citing, e.g., Ex. 1050 ¶ 25) (emphasis omitted). In other words, Ohsaki’s disclosure that a convex surface suppresses variation in reflected light would have motivated an artisan to add such a surface to Aizawa to improve detection efficiency of that sensor when placed on the palm side. *Id.* at 18.

Concerning Patent Owner’s third argument, Petitioner responds that adding a convex cover to Aizawa’s sensor would not decrease signal strength but, instead, “would improve Aizawa’s signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa’s photodetectors than would have with a flat cover” because such a cover improves light concentration across the entire lens and does not direct it only towards the center. *Id.* at 20–21 (citing, e.g., Ex. 1050 ¶¶ 31–34).

Petitioner asserts that Patent Owner and Dr. Madisetti “ignore[] the well-known principle of reversibility,” by which “a ray going from P to S will trace the same route as one from S to P.” Pet. Reply 22 (quoting Ex. 1051, 84, 92; Ex. 1052, 101, 110; Ex. 1053, 80:20–82:20). When applied to Aizawa’s sensor, Petitioner contends that any condensing benefit achieved by a convex cover would thus direct emitted light toward Aizawa’s peripheral detectors. *Id.* at 22–24 (citing, e.g., Ex. 1050 ¶¶ 35–43).

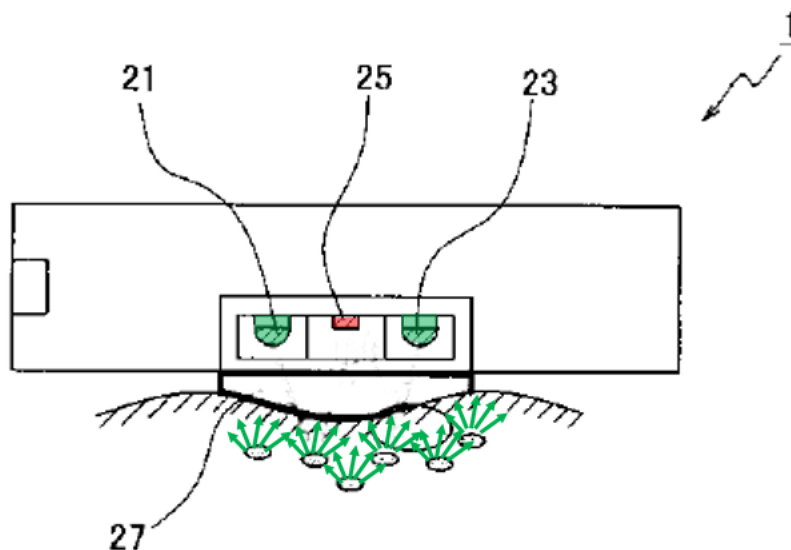
Although Dr. Madisetti refused to acknowledge “this basic principle of reversibility during deposition,” Petitioner contends this core concept of reversibility is applied in Aizawa. *Id.* at 24–25 (citing, e.g., Ex. 1006 ¶ 33; Ex. 1050 ¶ 44; Ex. 1055, 209:19–21).

Petitioner also asserts that Patent Owner and Dr. Madisetti overlook the fact that light rays reflected by body tissue will be scattered and diffuse and will approach the detectors “from various random directions and

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angles.” Pet. Reply 25–29 (citing, e.g., Ex. 1021, 52, 86, 90; Ex. 1050 ¶¶ 42–47; Ex. 1051, 841; Ex. 1052, 101; Ex. 1053, 80:20–82:20). This scattered and diffuse light, according to Petitioner, means that Ohsaki’s convex cover cannot “focus all light at the center of the sensor device,” as Patent Owner argues. *Id.* at 26. Instead, due to the random nature of this scattered light, Petitioner asserts that a person of ordinary skill in the art would have understood that “Ohsaki’s convex cover provides a slight refracting effect, such that light rays that may have missed the detection area are instead directed toward that area as they pass through the interface provided by the cover.” *Id.* at 27 (citing, e.g., Ex. 1050 ¶ 50). Petitioner applies this understanding to Aizawa, and asserts that using a cover with a convex protrusion in Aizawa would “enable backscattered light to be detected within a circular active detection area.” *Id.* (citing, e.g., Ex. 1021, 86, 90; Ex. 1050 ¶ 49).

Petitioner relies upon the following illustration of this alleged effect. Pet. Reply 30 (citing Ex. 1050 ¶ 54).



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The above illustration depicts backscattered light with Aizawa's sensor reflecting off user tissue in various directions, such that it impinges upon the peripheral detectors from various random angles and directions. *Id.*

According to Petitioner, this allows the detector to capture "light rays that otherwise would have missed the active detection area are instead directed toward that area." *Id.* at 31 (citing Ex. 1050 ¶ 55).

Petitioner also dismisses Patent Owner's reliance on Figure 14B of the '564 patent because it "is not an accurate representation of light that has been reflected from a tissue measurement site." Pet. Reply 28 (citing, e.g., Ex. 1050 ¶¶ 51–52). According to Petitioner, for example, "[t]he light rays (1420) shown in FIG. 14B are collimated (i.e., travelling paths parallel to one another), and each light ray's path is perpendicular to the detecting surface." *Id.* at 28–29.

Concerning Patent Owner's fourth argument, Petitioner responds that even if a flat surface might be less prone to scratching, that possible disadvantage would have been weighed against the "known advantages of applying Ohsaki's teachings," and would not negate a motivation to combine. *Id.* at 33 (citing, e.g., Ex. 1050 ¶ 60).

Patent Owner's Sur-reply

Concerning Patent Owner's first and second arguments, Patent Owner reiterates its position that Ohsaki's purported benefits attach only to a sensor with a rectangular convex surface that is located on the back of the wrist, and that "even small changes in sensor orientation or measurement location result in slippage." Sur-reply 1, 3–15, 8.

Concerning Patent Owner's third argument (that the convex cover would condense light toward the center and away from Aizawa's detectors),

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Patent Owner argues that Dr. Kenny and Petitioner have not overcome their admissions that a convex lens directs light toward the center. *Id.* at 15–16, 19–21. Patent Owner asserts that Petitioner’s Reply improperly presents several new arguments, relying on new evidence, as compared with the Petition. *Id.* at 16–19 (regarding reversibility). Moreover, Patent Owner argues that Petitioner’s discussion of the principle of reversibility is “irrelevant” because it “assumes conditions that are not present when tissue scatters and absorbs light.” *Id.* at 16–17. The random nature of backscattered light, in Patent Owner’s view, “hardly supports Petitioner’s argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed,” and is irrelevant to the central issue presented here of “whether changing Aizawa’s flat surface to a convex surface results in more light on Aizawa’s peripherally located detectors.” *Id.* at 18.

Patent Owner also asserts that Petitioner mischaracterizes Patent Owner’s position, which is not that Ohsaki’s cover with a convex protrusion “focuses *all* light to a single point” at the center of the sensor as Petitioner characterizes it. Sur-reply 20. Patent Owner’s position, rather, is that Petitioner has not shown that a person of ordinary skill in the art “would have been motivated to change Aizawa’s flat surface to a convex surface to improve signal strength.” *Id.* In Patent Owner’s view, by arguing that the convex cover provides only a “slight refracting effect,” Petitioner undermines its contention that providing such a cover would have improved detection efficiency. *Id.* at 20–21 (emphasis omitted).

Patent Owner also argues that Petitioner’s contention that a convex cover allows more light collection generally is a new theory not supported

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by Dr. Kenny’s original declaration. *Id.* at 20. Moreover, Patent Owner argues that Petitioner’s theory is “unavailing because it fails to consider the greater decrease in light at the detectors due to light redirection to a more central location.” *Id.* at 21 (emphasis omitted). According to Patent Owner, any light redirected from the sensor’s edge could not make up for the loss of signal strength from light redirected away from the detectors and toward the center. *Id.*

Concerning Patent Owner’s fourth argument, Patent Owner argues that Petitioner does not dispute Patent Owner’s position that a flat cover would be less prone to scratches and offers “*no* plausible advantages for its asserted combination.” *Id.* at 24. Moreover, Patent Owner argues that the risk of scratches undermines Petitioner’s argument of adding a convex cover to protect the elements within the sensor housing. *Id.* at 25.

Analysis

As noted above, Petitioner provides three rationales to support its contention that a person of ordinary skill in the art would have provided “a light permeable cover with a protruding convex surface,” such as that taught by Ohsaki, to Aizawa’s sensor: (1) to improve adhesion between the sensor and the user’s tissue; (2) to improve detection efficiency; and (3) to protect the elements within the sensor housing. Pet. 20–23 (citing, e.g., Ex. 1003 ¶¶ 67–70; Ex. 1009 ¶ 25). As further examined below, we determine all three rationales are supported by the evidence, and further that any single rationale standing alone would have been sufficient to establish a basis for the person of ordinary skill in the art to combine the references as proposed.

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Rationales 1 and 2

The evidence of record persuades us that adding a convex cover, such as that taught by Ohsaki, would have improved adhesion between the sensor and the user's skin, which would have increased the signal strength of the sensor. Ohsaki teaches as much:

[T]he convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby *it is prevented that the detecting element 2 slips off* the detecting position of the user's wrist 4. If the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4 as shown in Fig. 4B. However, in the case that the translucent board 8 has a convex surface like the present embodiment, the *variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8.* Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

Ex. 1009 ¶ 25 (emphasis added); *see also id.* ¶ 27 (“detecting element 2 is stably fixed”).

We credit Dr. Kenny's testimony that a person of ordinary skill in the art would have been motivated by such teachings to apply a cover with a convex surface to Aizawa to improve that similar device in the same way and to yield predictable results, i.e., to resist movement of the sensor on the user's wrist and to suppress variation. *See, e.g.,* Ex. 1003 ¶¶ 68 (“[T]his contact between the convex surface and the user's skin prevents slippage, which increases the strength of the signals obtainable by Ohsaki's [sensor].”), 70, 103 (One of ordinary skill would have understood that this “would have been used to realize improved adhesion between the user's

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wrist and the sensor’s surface, improve detection efficiency.”). We find persuasive Dr. Kenny’s explanation that the person of ordinary skill in the art “would have understood that a protruding convex cover would reduce the adverse effects of user movement on signals obtainable by photodetectors which are positioned to detect light reflected from user tissue.” Ex. 1050 ¶ 13.

Indeed, Ohsaki expressly compares the performance of a wrist-worn pulse wave sensor depending on whether translucent board 8 is convex or flat, and concludes the convex surface results in improved performance over the flat surface, especially when the user is moving. Ex. 1009, Figs. 4A–4B, ¶¶ 15, 25 (stating that with “a flat surface, the detected pulse wave is adversely affected by the movement of the user’s wrist 4,” and with “a convex surface like the present embodiment, the variation of the amount of the reflected light” collected by the sensor “is suppressed”). Ohsaki also states that, with a convex surface, “[i]t is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8.” *Id.* ¶ 25.

We also credit Dr. Kenny’s testimony that the proposed modification would have been within the skill level of an ordinary artisan. For example, Dr. Kenny testifies that one of ordinary skill in the art would have combined the teachings of Aizawa and Ohsaki as “[d]oing so would have amounted to nothing more than the use of a known technique to improve similar devices in the same way and combining prior art elements according to known methods to yield predictable results.” Ex. 1003 ¶ 67. In particular, one of ordinary skill in the art would have recognized that by incorporating Ohsaki’s convex surface, “the convex surface of the translucent board . . . is

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in intimate contact with the surface of the user's skin'; this contact between the convex surface and the user's skin prevents slippage, which increases the strength of the signals obtainable by Ohsaki's [sensor]." *Id.* ¶ 68 (citing Ex. 1009 ¶¶ 15, 17, 25, Figs. 1, 2, 4A, 4B).

In light of Ohsaki's express disclosure of the benefits of a convex cover, we credit Dr. Kenny's testimony that a person of ordinary skill in the art would have been motivated to modify Aizawa as proposed, and would have had a reasonable expectation of success in doing so.

We next address Patent Owner's first through third arguments, each of which implicates Petitioner's first and second asserted rationales of improved adhesion and detection efficiency.

Patent Owner's first argument is premised on the notion that Ohsaki's benefits only can be realized with a rectangular convex surface, because such a shape is required to avoid interacting with bones on the back of the user's forearm. PO Resp. 8–25. We disagree. Ohsaki does not disclose the shape of its convex cover, much less require it be rectangular. In fact, Ohsaki is silent as to the shape of the convex surface. Ohsaki discloses that sensor 1 includes detecting element 2, which includes package 5 within which the sensor components are located. Ex. 1009 ¶ 17. Ohsaki's convex surface is located on board 8, which is "attached to the opening of the package 5." *Id.* Ohsaki provides no further discussion regarding the shape of board 8 or its convex protrusion.

We disagree with Patent Owner's suggestion that the shape of the convex surface can be inferred to be rectangular from Ohsaki's Figures 1 and 2. PO Resp. 10–11. Ohsaki does not indicate that these figures are drawn to scale, or reflect precise dimensions or shapes of the convex

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surface. *See, e.g.*, Ex. 1009 ¶ 13 (“schematic diagram”); *see also* Pet. Reply 12–15; *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000) (“[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”).

To be clear, Ohsaki describes the shape of *detecting element 2* as rectangular: “[T]he length of the detecting element 2 from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side.” Ex. 1009 ¶ 19. Ohsaki also describes that detecting element 2 is aligned longitudinally with the user’s forearm: “[I]t is desirable that the detecting element 2 is arranged so that its longitudinal direction agrees with the longitudinal direction of the user’s arm,” to avoid slipping off. *Id.*; *see also id.* ¶ 9 (“The light emitting element and the light receiving element are arranged in the longitudinal direction of the user’s arm.”).

In light of this disclosed rectangular shape of detecting element 2, it is certainly possible that Ohsaki’s convex surface may be similarly shaped. But, it may not be. Contrary to Patent Owner’s argument, Ohsaki neither describes nor requires detecting element 2 to have the same shape as the convex surface of board 8. *Accord* Pet. Reply. 12–13 (noting also that Ohsaki’s board 8 “is not coextensive with the entire tissue-facing side of detecting element 2”). We have considered the testimony of both Dr. Kenny and Dr. Madisetti on this point. Ex. 1050 ¶¶ 8, 11–12, 18–23; Ex. 2004 ¶¶ 35–39 (relying on Ohsaki’s Figures 1–2 to support his opinion that the convex surface is rectangular). Dr. Madisetti’s reliance on the dimensions of Ohsaki’s figures is unpersuasive. *Hockerson-Halberstadt*, 222 F.3d at 956.

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We credit Dr. Kenny’s testimony that Ohsaki does not describe its convex surface as rectangular, because this testimony is most consistent with Ohsaki’s disclosure.

Further, Patent Owner suggests that the convex surface *must be* rectangular, in order to avoid interacting with bones in the user’s forearm. PO Resp. 18–23; Sur-reply 10 (“[A] POSITA would have understood Ohsaki’s convex board must also have a longitudinal shape oriented up-and-down the watch-side of the user’s wrist/forearm.”) (emphasis omitted). Although Ohsaki recognizes that interaction with these bones can cause problems, *see* Ex. 1009 ¶¶ 6, 19, we do not agree that the *only way* to avoid these bones is by aligning a rectangular cover with the longitudinal direction of the user’s forearm. For example, in the annotated Figures provided by Patent Owner, *see* PO Resp. 21, we discern that the circular sensor that purports to depict the proposed modification would *also* avoid the bones in the forearm if it were slightly smaller. Patent Owner provides no persuasive explanation to justify the dimensions it provides in this annotated figure, or to demonstrate that such a large sensor would have been required. Indeed, we discern that it would have been within the level of skill of an ordinary artisan to appropriately size a modified sensor to avoid these well-known anatomical obstacles. “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421. After all, an artisan must be presumed to know something about the art apart from what the references disclose. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962).

Finally, we do not agree with Patent Owner’s position that Ohsaki’s advantages apply only to rectangular convex surfaces. As discussed, Patent Owner has not shown that Ohsaki’s convex surface is rectangular at all.

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Moreover, even if Ohsaki's convex surface is rectangular, when discussing the benefits associated with a convex cover, Ohsaki does not limit those benefits to a cover of any particular shape. Instead, Ohsaki explains that "detecting element 2 is arranged on the user's wrist 4 so that the convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby it is prevented that the detecting element 2 slips off the detecting position of the user's wrist 4." Ex. 1009 ¶ 25; Ex. 1050 ¶ 18. Thus, we agree with Petitioner that Ohsaki's teaching of a convex surface would have motivated a person of ordinary skill in the art to add such a surface to Aizawa's circular-shaped sensor, to improve adhesion as taught by Ohsaki. *See, e.g.*, Pet. 20–23. Nothing in Ohsaki's disclosure limits such a benefit to a specific shape of the convex surface. Ex. 1050 ¶¶ 10–11, 14–23.

Moreover, Ohsaki contrasts the ability to properly receive reflected light with a convex surface as compared to a flat surface and notes that,

in the case that the translucent board 8 has a convex surface . . . the variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8. Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

Ex. 1009 ¶ 25; Ex. 1050 ¶¶ 12–13. Again, we agree with Petitioner that Ohsaki's teaching of a convex surface would have motivated a person of ordinary skill in the art to add such a surface to Aizawa's sensor, to improve signal strength, as taught by Ohsaki. *See, e.g.*, Pet. 21–23. Again, nothing

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in Ohsaki's disclosure limits such a benefit to the shape of the convex surface. Ex. 1050 ¶¶ 10–11, 14–23.

Accordingly, we do not agree that Ohsaki's disclosed advantages attach only to a rectangular convex surface, or would have been inapplicable to the proposed combination of Aizawa and Ohsaki.

We have also considered Patent Owner's arguments that Petitioner's proposed modification would disrupt Aizawa's "circular symmetry." See PO Resp. 23–25. We do not agree. Rather we agree with Petitioner that the proposed modification is not a bodily incorporation. That is, Petitioner does not propose a bodily incorporation of Ohsaki's rectangular board into Aizawa's circular cover. Pet. Reply 15–16. Petitioner proposes modifying Aizawa only to include a cover with a convex surface. Pet. 20. We agree with Petitioner that a person of ordinary skill in the art, "is also a person of ordinary creativity, not an automaton," and is capable of modifying Aizawa to, *inter alia*, minimize any gap when including a cover with a convex surface. Indeed, a purpose of Petitioner's proposed modification is to increase signal strength. See, e.g., Pet. 21–23. We discern that it would have been within the capability of an ordinarily skilled artisan to eliminate any gap that would have decreased signal strength or quality. Ex. 1050 ¶ 29.

We have considered Patent Owner's second argument, that Ohsaki's benefits are realized only when the sensor and convex surface are placed on the back of the user's wrist, which is the opposite side of the wrist taught by Aizawa. PO Resp. 25–38. We do not agree. As an initial matter, Petitioner does not propose bodily incorporating the references; Petitioner simply proposes adding a convex cover to Aizawa's sensor, without discussing where Aizawa's sensor is used. See, e.g., Pet. 20. In other words,

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Petitioner’s proposed modification does not dictate any particular placement, whether on the palm side or back side of the wrist.

To be sure, Ohsaki’s Figures 3A–3B compare the performance of detecting element 2, including its translucent board 8 having a convex protrusion, and show better performance when the element is attached to the back side of the wrist versus the front side of the wrist, when the user is in motion. *See* Ex. 1009 ¶¶ 23–24, Figs. 3A–3B. However, we do not agree that these figures support Dr. Madisetti’s conclusion that “Ohsaki indicates a convex surface only prevents slipping on the back (i.e., watch) side of the wrist in a specific orientation, but tends to slip when used in different locations or orientations” such as the palm side of the wrist—particularly in comparison to a flat surface such as Aizawa’s. Ex. 2004 ¶¶ 60, 73. Instead, Ohsaki acknowledges that, even when the detecting element is located “on the front [palm] side of the user’s wrist 4, *the pulse wave can be detected well* if the user is at rest.” Ex. 1009 ¶ 23 (emphasis added). Thus, Ohsaki discloses that, in at least some circumstances, a convex surface located on the front of the user’s wrist achieves benefits. *Id.* Notably, Ohsaki’s claims are not limited to detection during movement or exercise.

We credit, instead, Dr. Kenny’s testimony that a person of ordinary skill in the art would have understood from Ohsaki that a convex protrusion will help prevent slippage, even in the context of Aizawa’s sensor. *See* Ex. 1050 ¶¶ 10–11, 24–30. This is because the convex protrusion “promot[es] ‘intimate contact with the surface of the user’s skin,’” which “would have increased adhesion and reduced slippage of Aizawa’s sensor when placed on either side of a user’s wrist or forearm, and additionally

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would have provided associated improvements in signal quality.” *Id.* ¶¶ 29–30 (“additional adhesive effect”).

Dr. Madisetti testifies that

[b]ased on Aizawa’s teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki’s teaching that a convex surface tends to slip on the palm side of the wrist, a [person of ordinary skill in the art] would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa’s flat adhesive plate “to include a lens/protrusion . . . similar to Ohsaki’s translucent board” would not “improve adhesion.”

Ex. 2004 ¶ 78 (emphasis omitted); *see also id.* ¶ 76. We disagree with this reading of Aizawa. It is true that Aizawa’s plate 6 is illustrated as having a flat surface (Ex. 1006, Fig. 1(b)), and that Aizawa states the plate “improve[s] adhesion” (*id.* ¶ 13). Aizawa further states: “the above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10,” and “[t]hereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved.” *Id.* ¶ 26. These disclosures, however, indicate the improved adhesion is provided by the acrylic material of plate 6, not the shape of the surface of the plate, which is never specifically addressed. *See also id.* ¶¶ 30, 34 (“Since the acrylic transparent plate 6 is provided . . . adhesion between the pulse rate detector 1 and the wrist 10 can be improved.”). Aizawa does not associate this benefit of improved adhesion with the surface shape of the plate, but rather, with the existence of an acrylic plate to begin with. Thus, there is no teaching away from using a convex surface to improve the adhesion of Aizawa’s detector to the user’s wrist.

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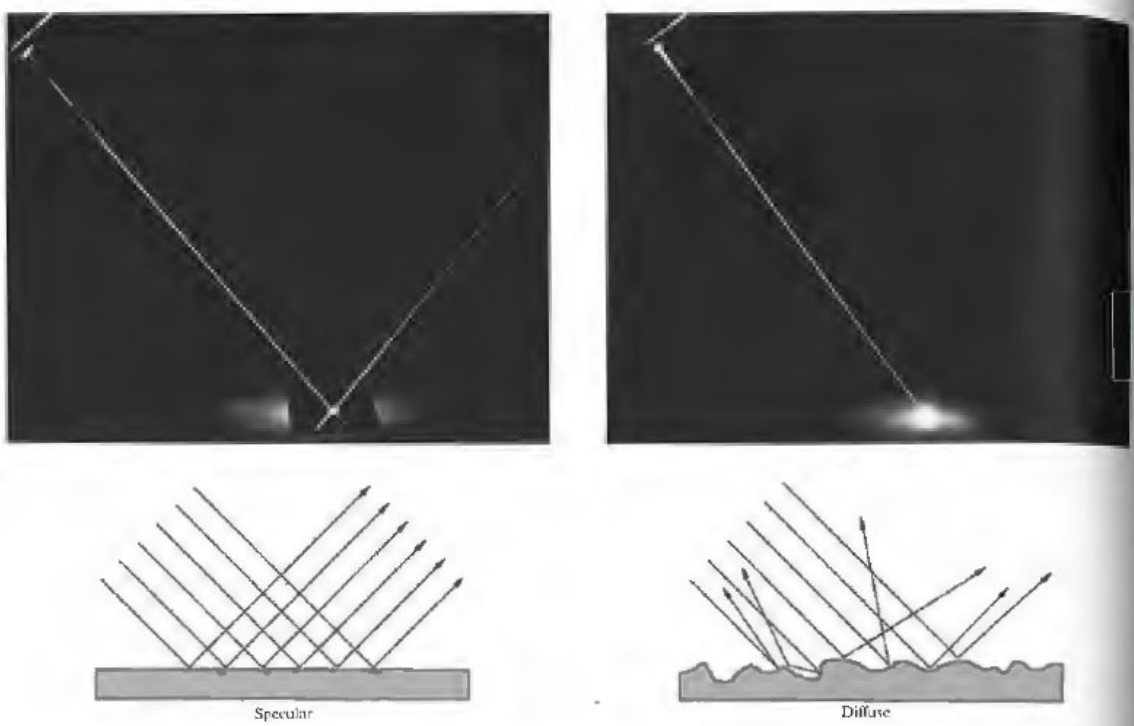
We have considered Patent Owner’s third argument that a convex cover would condense light away from Aizawa’s peripheral detectors, which Patent Owner alleges would decrease signal strength. PO Resp. 38–44. We disagree.

There appears to be no dispute that when emitted light passes through user tissue, the light diffuses and scatters as it travels. *See, e.g.*, Pet. Reply 29 (“[R]eflectance type pulse detectors detect light that has been ‘partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector,’” thus, a person of ordinary skill in the art “would have understood from Aizawa’s FIG. 1(a) that light that backscatters from the measurement site after diffusing through tissue reaches the circular active detection area provided by Aizawa’s detectors from various random directions and angles.”) (quoting Ex. 1021, 86); PO Sur-reply 17 (“Even Petitioner admits that tissue randomly scatters and absorbs light rays.”).

The light thus travels at random angles and directions, and no longer travels in a collimated and perpendicular manner. Exhibit 1051,⁶ Figure 4.12, illustrates the difference between diffuse and collimated light, and is reproduced below:

⁶ Eugene Hecht, *Optics* (2nd ed. 1990).

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This figure provides at left a photograph and an illustration showing incoming collimated light reflecting from a smooth surface, and at right a photograph and an illustration of incoming collimated light reflecting from a rough surface. *See* Ex. 1051, 87–88 (original page numbers). The smooth surface provides specular reflection, in which the reflected light rays are collimated like the incoming light rays. *See id.* The rough surface provides diffuse reflection, in which the reflected light rays travel in random directions. *See id.*; *see also* Ex. 1050 ¶ 46 (“A [person of ordinary skill in the art] would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area [provided] from various random directions and angles.”).

Dr. Kenny testifies that Aizawa “detect[s] light that has been ‘partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.’” Ex. 1050 ¶ 46 (quoting

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Ex. 1021, 86). Dr. Kenny further opines that a convex cover, when added to Aizawa's sensor with multiple detectors symmetrically arranged about a central light source, allows light rays that otherwise would have missed the detection area to instead be directed toward that area as they pass through the interface provided by the cover, thus increasing the light-gathering ability of Aizawa's sensor. *Id.* ¶¶ 46–49.

By contrast Dr. Madisetti testifies that “a convex [surface] condenses light passing through it towards the center of the sensor and away from the periphery.” Ex. 2004 ¶ 80; *see also id.* ¶¶ 80–82, 86. We have considered this testimony, however, Dr. Madisetti's opinions largely are premised upon the behavior of collimated and perpendicular light as depicted in Figure 14B of the challenged patent. *See id.* ¶ 82. Dr. Madisetti does not explain how light would behave when approaching the sensor from various angles, as it would after being reflected by tissue. *Id.* ¶¶ 84–88. In other words, even if Patent Owner is correct that the '564 patent's Figure 14B depicts light condensing toward the center, this is not dispositive to the proposed modification, because light reflected by a user's tissue is scattered and random, and is not collimated and perpendicular as shown in Figure 14B. Ex. 1001, Fig. 14B.

Patent Owner and Dr. Madisetti argue that “Petitioner and Dr. Kenny both admit that a convex cover condenses light towards the center of the sensor and away from the periphery,” in a different petition filed against a related patent, i.e., in IPR2020-01520. PO Resp. 39–41; Ex. 2004 ¶¶ 80–83. The cited portions of the Petition and Dr. Kenny's declaration from IPR2020-01520 discuss a decrease in the “mean path length” of a ray of light when it travels through a convex lens rather than through a flat surface.

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See, e.g., Ex. 2020 ¶¶ 118–120. We do not agree that this discussion is inconsistent with Dr. Kenny’s testimony here that, where light is reflected to the detectors at various random angles and directions, more light will reach Aizawa’s symmetrically disposed detectors when travelling through the convex surface than would be reached without such a surface, because light that might have otherwise missed the detectors now will be captured. *See, e.g.,* Ex. 1050 ¶¶ 49, 55 (“Ohsaki’s convex cover provides a slight refracting effect, such that light rays that may have otherwise missed the detection area are instead directed toward that area”). We do not discern that the convergence of a single ray of light toward the center, as discussed in IPR2020-01520, speaks to the aggregate effect on *all* light that travels through the convex surface.

We additionally do not agree with Patent Owner’s argument that Petitioner’s Reply presents new arguments and evidence that should have been first presented in the Petition, to afford Patent Owner an adequate opportunity to respond. *See* Sur-reply 16–19. The Petition proposed a specific modification of Aizawa to include a convex protrusion in the cover, for the purpose of increasing the light gathering ability of Aizawa’s device. *See* Pet. 19–23. The Patent Owner Response then challenged that contention, with several arguments that Petitioner’s proposed convex protrusion would not operate in the way the Petition alleges it would operate. *See* PO Resp. 38–44. This opened the door for Petitioner to provide, in the Reply, arguments and evidence attempting to rebut the contentions in the Patent Owner Response. *See* PTAB Consolidated Trial Practice Guide

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(Nov. 2019) (“Consolidated Guide”),⁷ 73 (“A party also may submit rebuttal evidence in support of its reply.”). This is what Petitioner did here. The Reply does not change Petitioner’s theory for obviousness; rather, the Reply presents more argument and evidence in support of the same theory for obviousness presented in the Petition. *Compare* Pet. 19–23, *with* Pet. Reply 20–32.

Rationale 3

Petitioner further contends that a person of ordinary skill in the art would have recognized that a cover with a protruding convex surface, such as that taught by Ohsaki, would “protect the elements within the sensor housing” of Aizawa. Pet. 47. We are persuaded that adding a convex cover, such as that taught by Ohsaki, would also protect the sensor’s internal components in a manner similar to Aizawa’s flat acrylic plate. Ex. 1003 ¶ 70; *see also* Ex. 1008 ¶ 15 (noting that a cover “protect[s] the LED or PD”).

We disagree with Patent Owner’s fourth argument that a person of ordinary skill in the art would not have modified Aizawa as proposed because a convex cover would be prone to scratches and because other alternatives existed. Patent Owner does not explain how the potential presence of scratches on a convex cover would preclude that cover’s ability to, nonetheless, protect the internal sensor components in Aizawa, as Petitioner proposes. That a convex cover may be more prone to scratches than Aizawa’s flat cover is one of numerous tradeoffs that a person of ordinary skill in the art would consider in determining whether the benefits

⁷ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

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of increased adhesion, signal strength, and protection outweigh the potential for a scratched cover. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). The totality of the final record does not support that the possibility of scratches alone would have dissuaded a person of ordinary skill in the art from the proposed modification, to achieve the benefits identified by Petitioner.

For the foregoing reasons, we are persuaded by Petitioner’s contentions.

- v. “[Id] one or more processors configured to: receive one or more signals from at least one of the at least four detectors, the one or more signals responsive to at least a physiological parameter of the user; and process the one or more signals to determine measurements of the physiological parameter”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses one or more processors. Pet. 51–52. According to Petitioner “a [person of ordinary skill in the art] would have understood that Aizawa’s drive detection circuit 24 and arithmetic circuit 3 are ‘one or more processors’ as they receive pulse wave data from the photodetectors and perform signal amplification and calculations to ‘comput[e] a pulse rate from the detected pulse wave data.’” *Id.* at 51 (citing Ex. 1006 ¶¶ 23, 28; Ex. 1003 ¶¶ 107–108).⁸

⁸ Petitioner further contends that Goldsmith also discloses a processor. Pet. 51–52. Because Aizawa teaches components of a computer system that operate on data, consistent with our construction of the term “processor,” further analysis of the combination of Aizawa, Ohsaki, and Goldsmith is not necessary for this particular claim limitation.

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vi. “[1e] a network interface configured to communicate with a mobile phone”

The cited evidence supports Petitioner’s undisputed contention that Goldsmith discloses a network interface configured to communicate with a mobile phone. Pet. 32–35, 53; *see, e.g.*, Ex. 1011 ¶ 52 (“The communications block 595 may be adapted to provide communication via one or more communications methods, such as RF 596, a USB 597, and IR 598.”). In addition, Petitioner provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 35. Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 55–60, 75–82, 112.

Petitioner further provides persuasive rationales for the combination of certain Goldsmith features with Aizawa and Ohsaki. Pet. 32–41, 35 (“to incorporate the Aizawa-Ohsaki sensor into Goldsmith’s WCD such that the sensor would have access to a network interface such as Goldsmith’s transceiver or communications block to facilitate remote monitoring, as described in Goldsmith”), 36 (“to incorporate the Aizawa-Ohsaki sensor into Goldsmith’s WCD in such a way as to enable measured pulse rate data to be stored in a storage device and retrieved for subsequent use”).

Patent Owner does not present any argument other than those we have already considered. PO Resp. 46 (“Petitioner does not argue Goldsmith cures the deficiencies in its proposed combination of Aizawa and Ohsaki.”).

vii. “[1f] a touch-screen display configured to provide a user interface”

The cited evidence supports Petitioner’s undisputed contention that Goldsmith discloses a touch-screen display configured to provide a user interface. Pet. 27–32, 53; *see, e.g.*, Ex. 1011 ¶ 86 (“[T]he display is a

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touchscreen display that may be activated by a user's hand.”). In addition, Petitioner provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 29. Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 59–60, 76–82, 113.

viii. “[1g] wherein the user interface is configured to display indicia responsive to the measurements of the physiological parameter”

The cited evidence supports Petitioner's undisputed contention that Goldsmith discloses the user interface is configured to display indicia responsive to the measurements of the physiological parameter. Pet. 27–32, 53–54. According to Petitioner, Goldsmith's “display 910 displays data directly from the sensor monitors, and data ‘received from a sensor transmitter on the patient's skin.’” *Id.* at 53 (citing Ex. 1011 ¶¶ 86–87, 102, Fig. 9A; Ex. 1003 ¶ 115).

ix. “[1h] an orientation of the user interface is configurable responsive to a user input”

The cited evidence supports Petitioner's undisputed contention that Goldsmith discloses an orientation of the user interface is configurable responsive to a user input. Pet. 55–59. According to Petitioner, Goldsmith's “display can be configured in various different ways to allow the interface to be consistent with the user's preferences and to correct the presentation of information that could be incorrect due to the scaling of graphs or incorrect resolutions.” *Id.* at 55–56 (citing Ex. 1011 ¶ 49). Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 118–123.

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- x. “[1i] a wall that surrounds at least the at least four detectors, wherein the wall operably connects to the substrate and the cover”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses holder 23, which is a wall that surrounds detectors 22, as well as other elements. Pet. 59–60; *see, e.g.*, Ex. 1006 ¶ 23 (“holder 23 for storing . . . light emitting diode 21 and the photodetectors 22”), Fig. 1(b). The cited evidence also supports Petitioner’s undisputed contention that Aizawa’s wall “connects to the substrate and the cover.” Pet. 60–61 (citing Ex. 1006 ¶¶ 23, 30). Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 124–125.

- xi. “[1j] a storage device configured to at least temporarily store at least the measurements of the physiological parameter”

The cited evidence supports Petitioner’s undisputed contention that Goldsmith’s device includes a storage device configured to at least temporarily store at least the measurements of the physiological parameter. Pet. 27–32, 61; *see, e.g.*, Ex. 1011 ¶ 95 (“[T]he heart rate or metabolic rate may be correlated to a level of exercise, such as low, medium or high, to store in the controller device memory.”). Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶ 126.

- xii. “[1k] a strap configured to position the physiological measurement device on the user”

The cited evidence supports Petitioner’s undisputed contention that Goldsmith’s device includes a strap configured to position the physiological measurement device on the user. Pet. 27–32, 61–63; *see, e.g.*, Ex. 1011 ¶ 85, Figs. 9A, 9B (“[D]evice 900 may include a wrist band 940 so that a user may wear the watch controller device 900 on his/her wrist.”).

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xiii. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

5. Dependent Claims 16 and 17

Dependent claim 16 ultimately depends from independent claim 1 and further recites “the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters.” Ex. 1001, 46:26–28.

Dependent claim 17 ultimately depends from independent claim 1 and further recites “the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters.” *Id.* at 46:30–32.

Petitioner contends that the sensor rendered obvious by the combined teachings of Aizawa, Ohsaki, and Goldsmith would have included a cover with a protruding convex surface. *See supra* § II.D.4.iv. With respect to claim 16, Petitioner contends that a person of ordinary skill in the art “would have found it obvious that a device designed to fit on a user’s wrist would be on the order of millimeters,” consistent with Ohsaki’s disclosure that the device is in “intimate contact” with the user’s skin. Pet. 77–78 (citing, e.g., Ex. 1003 ¶¶ 146–147). Petitioner also contends that an ordinarily skilled artisan would have taken user comfort into account when establishing the dimensions of the device’s convex cover. *Id.* at 78–79. With these considerations in mind, Petitioner contends that, “in order to provide a comfortable cover that prevents slippage, the convex surface should protrude a height between 1 millimeter and 3 millimeters,” because “there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable

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to the user.” *Id.* at 79 (citing, e.g., Ex. 1003 ¶¶ 147–148). With respect to claim 17, Petitioner incorporates its contentions regarding, *inter alia*, claim 16. Pet. 79; Ex. 1003 ¶ 149.

Patent Owner argues that none of the cited references disclose the claimed height range and that Petitioner relies on hindsight reconstruction. PO Resp. 47–50 (citing, e.g., Ex. 2004 ¶¶ 93–97). Patent Owner also characterizes Dr. Kenny’s testimony as conclusory and unsupported. *Id.* at 50–51. Patent Owner also alleges that the benefit “of reducing the main optical path lengths” is achieved at these dimensions. Tr. 31:8–15.

Petitioner is correct that, “[w]hen there . . . are a finite number of identified, predictable solutions, a person of ordinary skill [in the art] has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product . . . of ordinary skill and common sense.” *KSR*, 550 U.S. at 421. Petitioner has shown sufficiently that only a finite number of solutions existed with respect to the height of a convex protrusion on a tissue-facing sensor, which would have met the art-recognized goals of both (1) intimate contact between the sensor’s surface and the user and (2) user comfort. *See, e.g.*, Ex. 1009 ¶¶ 6, 25. Bearing in mind these considerations, we credit Dr. Kenny’s testimony that it would have been obvious, “in order to provide a comfortable cover that prevents slippage, [that] the convex surface should protrude a height between 1 millimeter and 3 millimeters,” as recited in claim 16, and which further includes the claimed range of 2 to 3 millimeters as recited in claim 17. Ex. 1003 ¶ 148. Further, the record does not support that any new and unexpected results were achieved at the claimed height greater than 2 millimeters and less than 3 millimeters. *See, e.g.*, Ex. 1001, 23:43–50 (“The

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height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.”).

We have considered Patent Owner’s argument, and Dr. Madisetti’s cited testimony. However, it is not dispositive that none of Aizawa, Ohsaki, or Goldsmith teaches the claimed range. PO Resp. 48–50; Ex. 2004 ¶¶ 95–97. Petitioner relies upon the knowledge, ability, and creativity of a person of ordinary skill in the art, not the teachings of a specific reference. Notably, Dr. Madisetti does not dispute Dr. Kenny’s position that there were a finite number of options available for the height of the convex surface. Ex. 2004 ¶¶ 95–98. Therefore, we do not agree that Petitioner’s contentions are rooted in impermissible hindsight. *See, e.g., In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) (“Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.”). As for the alleged benefit at the specific ranges described in the Specification, we agree with Petitioner that other considerations are relevant, such as user comfort and other attributes, that would have motivated a person of ordinary skill in the art to design within the claimed ranges. *See* Tr. 80:7–14; Ex. 1001, 23:43–50.

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Accordingly, for the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 16 and 17 would have been obvious over the cited combination of references.

6. Dependent Claims 2–10, 13–15, and 18–30

Petitioner also contends that claims 2–10, 13–15, and 18–30 would have been obvious based on the same combination of prior art addressed above. These challenged claims all depend directly or indirectly from independent claim 1. Petitioner identifies teachings in the prior art references that teach the limitations of these claims, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 64–77, 80–91. Petitioner also supports its contentions for these claims with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 129–145, 150–170.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1. PO Resp. 46–47 (“[T]he Petition fails to establish that independent claim 1 is obvious in view of the cited references of Ground 1 and therefore fails to establish obviousness of any of the challenged dependent claims.”).

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that claims 2–10, 13–15, and 18–30 would have been obvious over the combined teachings of Aizawa, Ohsaki, and Goldsmith for the reasons discussed in the Petition and as supported by the testimony of Dr. Kenny.

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For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 1–10 and 13–30 would have been obvious over the cited combination of references.

*E. Obviousness over the Combined Teachings of
 Aizawa, Ohsaki, Goldsmith, and Sherman*

Petitioner contends that claim 11 of the '564 patent would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, and Sherman. Pet. 91–95; *see also* Pet. Reply 37–40. Patent Owner disagrees. PO Resp. 51–52; *see also* Sur-reply 27–28.

Based on our review of the parties' arguments and the cited evidence of record, we determine that Petitioner has met its burden of showing by a preponderance of the evidence that claim 11 is unpatentable.

1. Sherman (Ex. 1013)

Sherman is a patent titled “Magnetic Clasp for Wristwatch Strap,” and it relates to use of magnetizable material embedded in thermoplastic material with rows of alternating magnetic poles. Ex. 1013, codes (54), (57). Sherman discloses a magnetic fastening mechanism for “wrist instruments,” such as wristwatches. *Id.* at 1:4–10. Sherman's system provides “an improved clasp for a flexible strap which eliminates buckles or other types of protruding mechanisms” and is “secured, yet easy to engage when desired.” *Id.* at 2:1–11. As shown below in Figure 2 of Sherman, the mechanism includes a pair of flexible strap ends having “permanently magnetizable material” of opposite polarities in addition to “mutually nesting uniformly spaced protuberances and indentations.” *Id.* at 2:43–62, Fig. 2.

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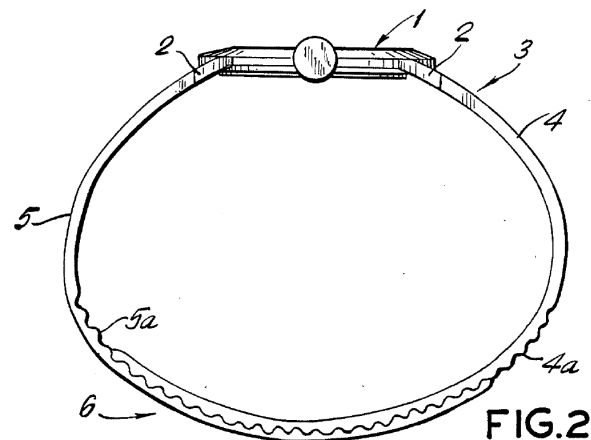


Figure 2 of Sherman depicts an end elevational view showing the wristwatch and strap with transverse ridges 4a and 5a incorporating magnetic securing materials. *Id.*

2. Dependent Claim 11

Claim 11 additionally requires “a magnet configured to be used as a connecting mechanism.” Ex. 1001, 46:8–9. Petitioner contends that it would have been obvious for a person of ordinary skill in the art to have modified the sensor system of Aizawa-Ohsaki-Goldsmith to integrate a magnetic connection as taught by Sherman. Pet. 93–95.

Petitioner’s Contentions

Petitioner contends that although Goldsmith generally discloses a fastener, Goldsmith “provides no details describing the fastener,” but that a person of ordinary skill in the art “would have been motivated to look to other wearable, wrist worn devices such as Sherman’s, for details regarding a mechanism for fastening a monitoring device.” Pet. 93 (citing Ex. 1003 ¶ 171). Petitioner contends a person of ordinary skill in the art would have been motivated to add Sherman’s magnetic connection in order to be more

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visually appealing, prevent corners from catching upon clothing, and to prevent broken connectors or accidental snagging. *Id.* (citing Ex. 1013, 1:11–24; Ex. 1003 ¶ 171).

Patent Owner's Contentions

Patent Owner disputes Petitioner's contentions. Patent Owner argues that Petitioner's proposed combination relies on Sherman solely for its alleged disclosure of a magnetic connector, but Ohsaki already includes a series of dedicated belts designed to exert a specific pressure on the user's wrist. PO Resp. 51 (citing Ex. 1009 ¶ 18). Patent Owner alleges that a person of ordinary skill in the art would have understood that any advantage from Ohsaki's convex board would also require Ohsaki's specific attachment arrangement, which includes belts and a cushion to prevent movement, yet, Petitioner does not explain how Sherman would have allowed consistent attachment pressure for its sensor as required by Ohsaki. *Id.* at 52 (citing Ex. 1009 ¶ 18); *see also* Sur-reply 27 ("Ohsaki uses specific dedicated belts to keep sensor body, detecting element, and cushion aligned."). Thus, Patent Owner contends that the person of ordinary skill in the art "would not have been motivated to incorporate Sherman's magnetic attachment mechanism into Petitioner's proposed combination." PO Resp. 52 (citing Ex. 2004 ¶ 101); *see also* Sur-reply 27–28.

Analysis

We are persuaded by Petitioner's evidence and argument that a person of ordinary skill in the art would have been motivated to combine Sherman's teaching of a magnetic connection in the existing combination of references. We find persuasive Dr. Kenny's testimony that a person of ordinary skill in

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the art would have understood from Ohsaki itself that a cushion designed to exert a specific pressure is not required to obtain the benefits described in relation to Ohsaki's board. Ex. 1050 ¶¶ 67–69 (noting that Ohsaki's cushion is on the back side whereas the modified connection “would be on the front side”) (citing Ex. 1009, Fig. 1). Further, we are persuaded by Dr. Kenny's testimony that “[t]he combination involves nothing more than applying a known technique to fasten two ends of a strap for attaching a wrist worn device to a user's arm.” Ex. 1003 ¶ 174. In light of the totality of the record, including Dr. Kenny's testimony, we determine that a person of ordinary skill in the art would have been motivated to employ Sherman's magnetic connector because the pressure range required for Ohsaki's benefits could be achieved by any number of connection fastening mechanisms.

Further, Patent Owner's arguments do not persuasively address Petitioner's proposed combination. *See* Pet. 19–23, 91–95. Ohsaki was relied upon for its teaching that a convex surface protruding into a user's skin will, *inter alia*, prevent slippage. *See id.*; *see also* Ex. 1050 ¶ 73; Ex. 1009, 25, Figs. 4A, 4B. As discussed above, we found persuasive Dr. Kenny's testimony that a person of ordinary skill in the art would have had reason, in view of that teaching, to modify the Aizawa's sensor's flat cover to include a protrusion, so as to improve adhesion between the user's wrist and the sensor's surface, improve detection efficiency, and protect the elements within the sensor housing. *See* Ex. 1003 ¶¶ 103–106. The resulting sensor features Aizawa's cover modified in view of Ohsaki, but does not include Ohsaki's belt connector. Ex. 1050 ¶ 7. Likewise, Patent Owner does not effectively rebut Dr. Kenny's testimony that a person of

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ordinary skill in the art would have integrated a magnetic connector in the combination of references in view of Sherman for reasons related to engagement and user comfort. *See* PO Resp. 51–52; Ex. 1003 ¶¶ 173–174 (“because it provided details of a wrist-worn device fastening mechanism that addresses the above-noted problems, is easy to engage, and improves user comfort”); Ex. 1050 ¶¶ 68–69.

3. Conclusion

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 11 would have been obvious over the cited combination of references.

F. Obviousness over the Combined Teachings of Aizawa, Ohsaki, Goldsmith, and Rantala

Petitioner contends that claim 12 of the ’564 patent would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, and Rantala. Pet. 95–99; *see also* Pet. Reply 40. Patent Owner disagrees. PO Resp. 51–52;⁹ *see also* Sur-reply 28.

Based on our review of the parties’ arguments and the cited evidence of record, we determine that Petitioner has met its burden of showing by a preponderance of the evidence that claim 12 is unpatentable.

1. Rantala (Exhibit 1022)

Rantala is a patent titled “Pulse Oximeter,” and it relates to minimizing the power consumption in a pulse oximeter without

⁹ Although Patent Owner’s heading lists Grounds 2 and 3, Patent Owner only discusses ground 2.

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compromising on performance. Ex. 1022, codes (54), (57). Figure 1 of Rantala is reproduced below.

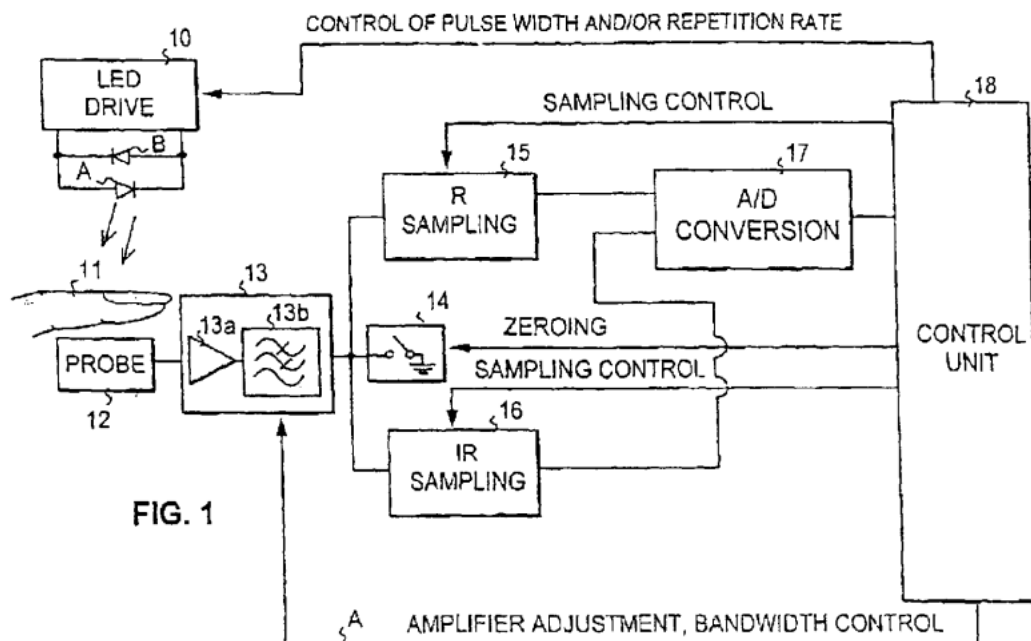


Figure 1 illustrates an exemplary pulse oximeter. *Id.* at 4:26–27. As depicted in Figure 1, Rantala’s pulse oximeter includes a control unit 18 connected to a LED Drive 10 that drives LEDs A and B to emit light at different wavelengths. *Id.* at 4:47–5:13. Rantala explains that to optimize and minimize power consumption in the pulse oximeter, control unit 18 changes at least one parameter, such as the pulse width, pulse repetition rate, and pulse amplitude, of the duty cycle of the pulse train driving the LEDs. *Id.* at 5:13–36. Exemplary pulse trains generated by the control unit are shown in Rantala’s Figures 3a and 4a, reproduced below.

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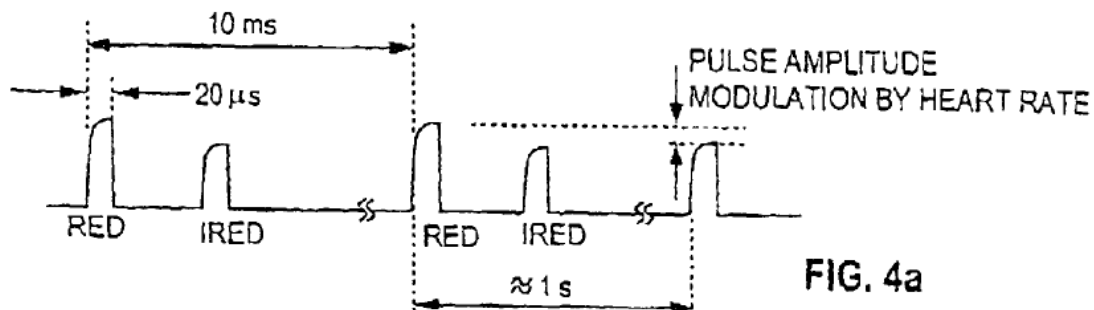
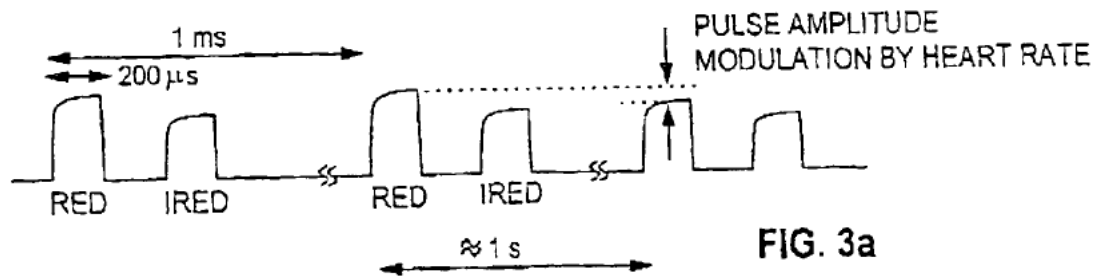


Figure 3a (top) “illustrates the timing sequence of the detector signal when a high duty cycle pulse sequence is used,” and Figure 4a (bottom) illustrates “the timing sequence of the detector signal when a low duty cycle pulse sequence is used.” *Id.* at 4:31–32, 38–39. Exemplary pulse trains generated by the control unit and depicted in Rantala’s Figures 3a and 4a show the pulse width of the pulse train in Figure 4a being narrower than the pulse width of the pulse train in Figure 3a. *Id.* at 6:20–56.

2. Dependent Claim 12

Claim 12 additionally requires “the one or more processors are further configured to modulate a duty cycle of one or more of the one or more emitters, and wherein the modulation includes pulse width time slots and off time slots.” Ex. 1001, 46:11–14. Petitioner contends that it would have been obvious for a person of ordinary skill in the art to have modified the

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processors of Aizawa-Ohsaki-Goldsmith to modulate a duty cycle of one or more of the one or more emitters as taught by Sherman. Pet. 95–99.

The cited evidence supports Petitioner’s undisputed contention that Rantala’s device includes one or more processors are further configured to modulate a duty cycle of one or more of the one or more emitters, and wherein the modulation includes pulse width time slots and off time slots. Pet. 95–99; *see, e.g.*, Ex. 1022, 6:22–29 (“The power control scheme of the present invention uses a high duty cycle pulse train only when the desired signal-to-noise ratio cannot otherwise be reached, i.e. the situation of [Figures] 3a to 3d” or “in [Figures] 4a to 4d the pulse oximeter is a narrow pulse oximeter where the LEDs are activated as briefly as possible in order to save power.”). Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 64, 176–179.

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 12 would have been obvious over the cited combination of references.

G. Obviousness over the Combined Teachings of Aizawa, Ohsaki, Goldsmith, and Ali

Petitioner challenges the patentability of claims 1–10 and 13–30 based on the combination of Aizawa, Ohsaki, Goldsmith, and Ali. Pet. 9, 99–102. Ali is relied upon to teach limitation [1h] which reads: “an orientation of the user interface is configurable responsive to a user input.” Petitioner contends that remaining claim limitations [1a]–[1g] and [1i]–[1k] are unpatentable for the same reasons raised with respect to the challenge of claim 1 based on the combination of Aizawa, Ohsaki, and Goldsmith.

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Pet. 99 (“Prior art mappings and arguments for all claim features other than [1h] in Ground 4 are the same as in Ground 1.”).

1. Overview of Ali

Ali is a U.S. patent titled “Universal/Upgrading Pulse Oximeter,” and discloses a portable pulse oximeter unit for measuring a patient’s oxygen saturation or other related physiological parameters. Ex. 1019, codes (54), (57). The portable unit includes a display configured to display an image that is “rotatable, either manually . . . or as a function of orientation.” *Id.* at code (57). Figures 8B and 8C of Ali are reproduced below.

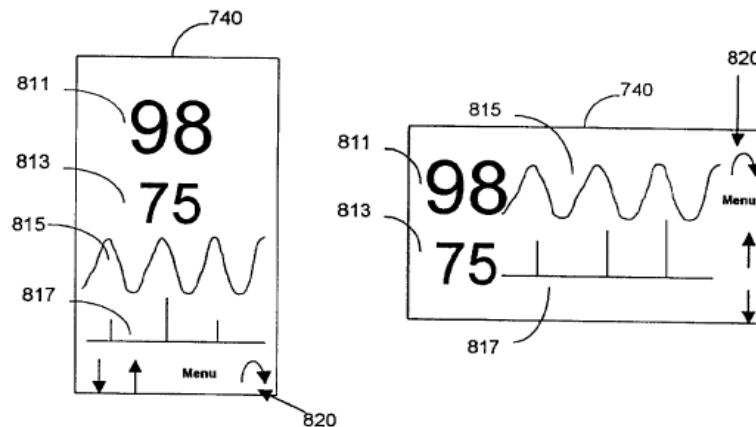


FIG. 8B

FIG. 8C

Figure 8B (left) depicts the display of the portable pulse oximeter in portrait mode, and Figure 8C (right) depicts the display of the portable oximeter in landscape mode. *Id.* at 11:62–64. The portrait mode and landscape mode are determined by a gravity-activated tilt sensor or a display mode key. *Id.* at 11:64–12:7.

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2. *Independent Claim 1 (Aizawa, Ohsaki, Goldsmith, and Ali)*

Petitioner presents undisputed contentions that claim 1 would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, and Ali. Pet. 99–102.

For this Ground, Patent Owner does not present any argument other than those we have already considered above with respect to the Ground based on Aizawa, Ohsaki, and Goldsmith. PO Resp. 52–53 (“Petitioner does not rely on Ali to fix the deficiencies in Ground 1. The Board should thus reject Ground 4 for the same reasons as Ground 1.”).

i. [1a]–[1g] and [1i]–[1k]

The cited evidence supports Petitioner’s contentions regarding these limitations. Pet. 41–54, 59–63.

Petitioner contends claim limitations [1a]–[1g] and [1i]–[1k] are unpatentable for the same reasons raised with respect to Petitioner’s challenge based on Aizawa, Ohsaki, and Goldsmith. Pet. 99. The ground based on Aizawa, Ohsaki, and Goldsmith is addressed *supra* at §§ (II)(D)(4)(i)–(xii). For the reasons discussed in these sections, Petitioner’s stated reasoning with respect to these limitations, and the basis for combining Aizawa, Ohsaki, and Goldsmith, is sufficiently supported, including by the testimony of Dr. Kenny.

ii. “[h] an orientation of the user interface is configurable responsive to a user input”

The cited evidence supports Petitioner’s undisputed contentions regarding this limitation and the rationale for combining Ali with Aizawa, Ohsaki, and Goldsmith. Pet. 99–102.

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As noted in our analysis above, Petitioner proposes integrating the pulse wave sensor of Aizawa (as modified by Ohsaki) into the watch controller device of Goldsmith, so that the modified sensor can transmit data to Goldsmith's touchscreen. Pet. 41. Goldsmith notes a problem in displaying images as a result of the display of a controller device and infusion pump having two different resolutions. Ex. 1011 ¶ 49.

Acknowledging the image display problem described in Goldsmith, Petitioner contends images displayed on the touchscreen user interface of the pulse wave sensor of Aizawa (as modified by Ohsaki and Goldsmith) "can be incorrect due to screen formatting, scaling, and resolution issues." Pet. 101 (citing Ex. 1011 ¶ 49). Goldsmith further discloses that its display is customizable with different backgrounds, fonts, wallpapers, or font sizes. Ex. 1011 ¶¶ 102, 104.

Figures 8B and 8C of Ali disclose a portable pulse oximeter that displays images, such as pulse rate data, in portrait mode or alternatively in landscape mode. Ex. 1019, 11:62–64, 12:8–12. Petitioner contends "to address problems in displaying graphs and text as described in Goldsmith, a POSITA would have included Ali's capability to select user interface orientation through a user input such that the user may have greater control over the display and enjoy an improved viewing experience." Pet. 101–102. Dr. Kenny testifies:

Implementing Ali's capability to select user interface orientation in [Aizawa, Ohsaki, and Goldsmith's physiological measurement device] would have been predictable at least because it would have involved incorporating a feature that was simple to implement and known in the industry. For instance, Ali concedes that its user interface orientation selection feature can easily be implemented through a software program for

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modifying the display of information. . . . Furthermore, this combination would have addressed a known issue in Goldsmith’s user interface, and would require nothing more than applying a known technique, as described by Ali.

Ex. 1003 ¶ 184; *also see* Pet. 102 (citing Ex. 1003).

Petitioner’s stated reasoning is sufficiently supported, including by the un rebutted testimony of Dr. Kenny.

iii. Summary

We have considered the evidence and arguments of record, including those directed to ground 1 addressed above, and we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 12 would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, and Ali for the reasons discussed in the Petition and as supported by the testimony of Dr. Kenny.

3. Dependent Claims 2–10 and 13–30

Petitioner also contends that claims 2–10 and 13–30 would have been obvious based on the same combination of prior art addressed above. These challenged claims all depend directly or indirectly from independent claim 1. Petitioner identifies teachings in the prior art references that teach the limitations of these claims, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 99–102. Petitioner also supports its contentions for these claims with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 180–184.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1. PO Resp. 52–53 (“Petitioner does not rely on Ali to fix the deficiencies in

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Ground 1. The Board should thus reject Ground 4 for the same reasons as Ground 1.”).

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that claims 2–10 and 13–30 would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, and Ali for the reasons discussed in the Petition and as supported by the testimony of Dr. Kenny.

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 1–10 and 13–30 would have been obvious over the cited combination of references.

H. Obviousness over the Combined Teachings of Aizawa, Ohsaki, Goldsmith, Ali, and Sherman

Petitioner presents undisputed contentions that claim 11 would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, Ali, and Sherman. Pet. 102–103.

Patent Owner does not present any argument for claim 11 other than those we have already considered above with respect to the Ground based on Aizawa, Ohsaki, and Goldsmith. PO Resp. 53 (“Grounds 5[–]6 only address dependent claims and do not fix the deficiencies in Ground 4. The Board should thus reject Grounds 5[–]6 for the same reasons as Ground 1.”).

For the reasons discussed above in § II.E, Petitioner identifies teachings in the prior art references that teach or suggest the limitations of claim 11, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny.

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Ex. 1003 ¶¶ 185–186. For the same reasons, and having considered the evidence and arguments of record, including those directed to claim 1 and addressed above, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 11 would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, Ali, and Sherman for the reasons discussed in the Petition and as supported by the testimony of Dr. Kenny. *See, e.g.*, Ex. 1013, 1:4–24; Ex. 1003 ¶¶ 171–174, 185–186.

I. Obviousness over the Combined Teachings of Aizawa, Ohsaki, Goldsmith, Ali, and Rantala

Petitioner presents undisputed contentions that claim 12 would have been obvious over the combined teachings of Aizawa, Ohsaki, Goldsmith, Ali, and Rantala. Pet. 102–103.

Patent Owner does not present any argument for claim 12 other than those we have already considered with respect to claim 1. PO Resp. 53 (“Grounds 5[–]6 only address dependent claims and do not fix the deficiencies in Ground 4. The Board should thus reject Grounds 5[–]6 for the same reasons as Ground 1.”).

For the reasons discussed above in § II.F, Petitioner identifies teachings in the prior art references that teach or suggest the limitations of claim 12, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 185–186. For the same reasons, and having considered the evidence and arguments of record, including those directed to claim 1 and addressed above, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 12 would have been obvious over

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the combined teachings of Aizawa, Ohsaki, Goldsmith, Ali, and Rantala for the reasons discussed in the Petition and as supported by the testimony of Dr. Kenny. *See, e.g.*, Ex. 1022, 6:22–29; Ex. 1003 ¶¶ 176–179, 185–186.

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III. CONCLUSION

In summary:¹⁰

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–10, 13–30	103	Aizawa, Ohsaki, Goldsmith	1–10, 13–30	
11	103	Aizawa, Ohsaki, Goldsmith, Sherman	11	
12	103	Aizawa, Ohsaki, Goldsmith, Rantala	12	
1–10, 13–30	103	Aizawa, Ohsaki, Goldsmith, Ali	1–10, 13–30	
11	103	Aizawa, Ohsaki, Goldsmith, Ali, Sherman	11	
12	103	Aizawa, Ohsaki, Goldsmith, Ali, Rantala	12	
Overall Outcome			1–30	

¹⁰ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–30 of the '564 patent have been shown to be unpatentable;

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 10,624,564 B1

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01716
Patent 10,702,194 B1

Before JOSIAH C. COCKS, ROBERT L. KINDER, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

Apple Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–30 (“challenged claims”) of U.S. Patent No. 10,702,194 B1 (Ex. 1001, “the ’194 patent”). Paper 2 (“Pet.”). Masimo Corporation (“Patent Owner”) waived filing a preliminary response. Paper 6 (“PO Waiver”). We instituted an *inter partes* review of all challenged claims 1–30 on all grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 7 (“Inst. Dec.”).

After institution, Patent Owner filed a Response (Paper 15, “PO Resp.”) to the Petition, Petitioner filed a Reply (Paper 19, “Pet. Reply”), and Patent Owner filed a Corrected Sur-reply (Paper 28, “PO Sur-reply”). An oral hearing was held on February 9, 2022, and a transcript of the hearing is included in the record. Paper 34 (“Tr.”).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has met its burden of showing, by a preponderance of the evidence, that challenged claims 1–30 of the ’194 patent are unpatentable.

B. Related Matters

The parties identify the following matters related to the ’194 patent: *Masimo Corporation v. Apple Inc.*, Civil Action No. 8:20-cv-00048 (C.D. Cal.) (filed Jan. 9, 2020);

Apple Inc. v. Masimo Corporation, IPR2020-01520 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,258,265 B1);

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Apple Inc. v. Masimo Corporation, IPR2020-01521 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,292,628 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01523 (PTAB Sept. 9, 2020) (challenging claims of U.S. Patent No. 8,457,703 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01524 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,433,776 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01526 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 6,771,994 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01536 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01537 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01538 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01539 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01713 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,624,564 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01714 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01715 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01722 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01723 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01733 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,195 B1); and

Apple Inc. v. Masimo Corporation, IPR2020-01737 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,709,366 B1).

Pet. 91; Paper 3, 1–4.

Patent Owner further identifies the following pending patent applications, among other issued and abandoned applications, that claim priority to, or share a priority claim with, the '194 patent:

U.S. Patent Application No. 16/834,538;

U.S. Patent Application No. 16/449,143; and

U.S. Patent Application No. 16/805,605.

Paper 3, 1–2.

C. The '194 Patent

The '194 patent is titled “Multi-Stream Data Collection System for Noninvasive Measurement of Blood Constituents,” and issued on July 7, 2020, from U.S. Patent Application No. 16/829,536, filed March 25, 2020. Ex. 1001, codes (21), (22), (45), (54). The '194 patent claims priority through a series of continuation and continuation-in-part applications to Provisional Application Nos. 61/078,228 and 61/078,207, both filed July 3, 2008. *Id.* at codes (60), (63).

The '194 patent discloses a two-part data collection system including a noninvasive sensor that communicates with a patient monitor. *Id.* at 2:49–51. The sensor includes a sensor housing, an optical source, and several photodetectors, and is used to measure a blood constituent or analyte, e.g., oxygen or glucose. *Id.* at 2:40–46, 3:8–9. The patient monitor includes a

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display and a network interface for communicating with a handheld computing device. *Id.* at 2:56–59.

Figure 1 of the '194 patent is reproduced below.

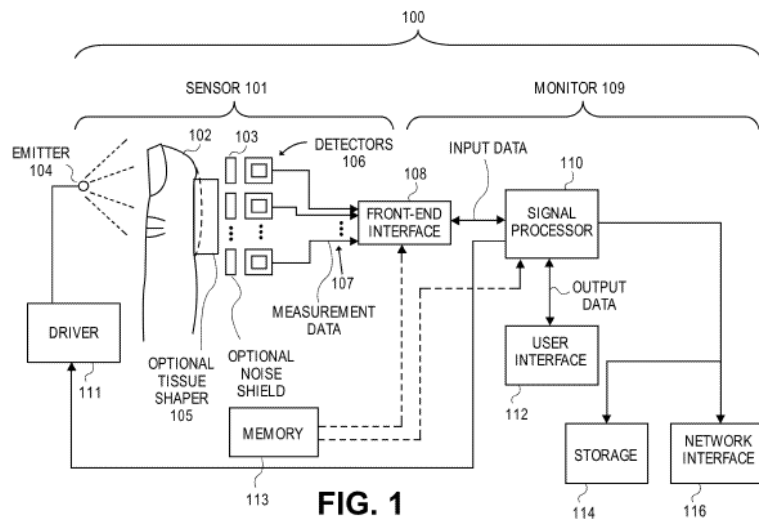


Figure 1 illustrates a block diagram of data collection system 100 including sensor 101 and monitor 109. *Id.* at 11:56–67. Sensor 101 includes optical emitter 104 and detectors 106. *Id.* at 12:1–5. Emitters 104 emit light that is attenuated or reflected by the patient’s tissue at measurement site 102. *Id.* at 14:11–16. Detectors 106 capture and measure the light attenuated or reflected from the tissue. *Id.* In response to the measured light, detectors 106 output detector signals 107 to monitor 109 through front-end interface 108. *Id.* at 14:16–19, 36–42. Sensor 101 also may include tissue shaper 105, which may be in the form of a convex surface that: (1) reduces the thickness of the patient’s measurement site; and (2) provides more surface area from which light can be detected. *Id.* at 11:7–23.

Monitor 109 includes signal processor 110 and user interface 112. *Id.* at 15:27–29. “[S]ignal processor 110 includes processing logic that determines measurements for desired analytes . . . based on the signals received from the detectors.” *Id.* at 15:32–35. User interface 112 presents

the measurements to a user on a display, e.g., a touch-screen display. *Id.* at 15:57–67. The monitor may be connected to storage device 114 and network interface 116. *Id.* at 16:4–22.

The '194 patent describes various examples of sensor devices. Figures 14D and 14F, reproduced below, illustrate detector portions of sensor devices.

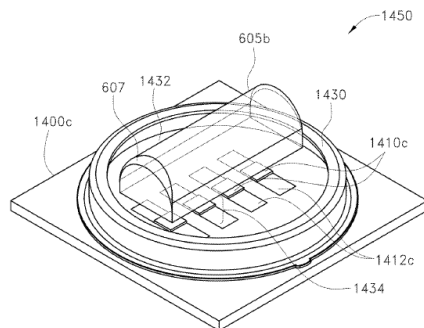


FIG. 14D

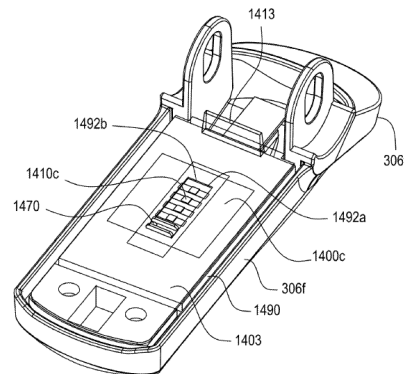
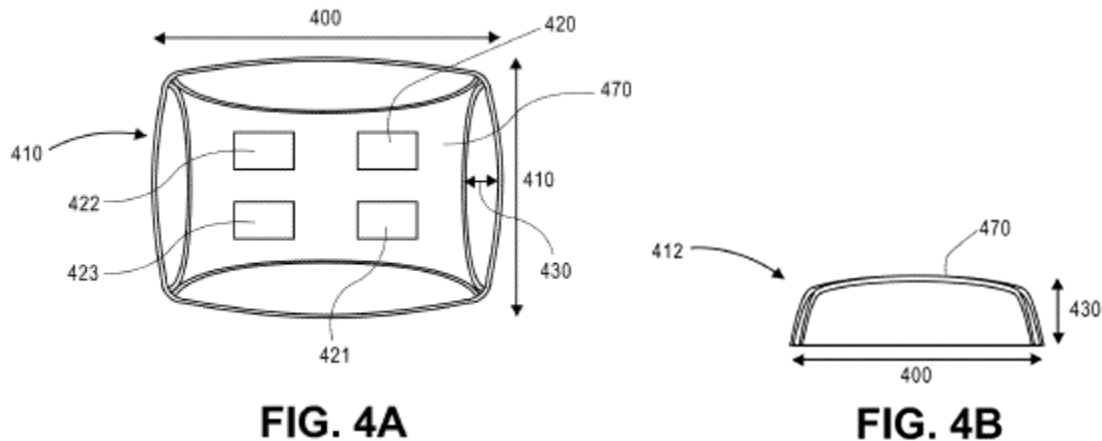


FIG. 14F

Figure 14D illustrates portions of a detector submount and Figure 14F illustrates portions of a detector shell. *Id.* at 6:54–57. As shown in Figure 14D, multiple detectors 1410c are located within housing 1430 and under transparent cover 1432, on which protrusion 605b (or partially cylindrical protrusion 605) is disposed. *Id.* at 35:51–54, 36:45–52. Figure 14F illustrates a detector shell 306f including detectors 1410c on substrate 1400c. *Id.* at 37:25–33. Substrate 1400c is enclosed by shielding enclosure 1490 and noise shield 1403, which include window 1492a and window 1492b, respectively, placed above detectors 1410c. *Id.* Alternatively, cylindrical housing 1430 may be disposed under noise shield 1403 and may enclose detectors 1410c. *Id.* at 37:63–65.

Figures 4A and 4B, reproduced below, illustrate an alternative example of a tissue contact area of a sensor device.



Figures 4A and 4B illustrate arrangements of protrusion 405 including measurement contact area 470. *Id.* at 23:30–36. “[M]easurement site contact area 470 can include a surface that molds body tissue of a measurement site.” *Id.* “For example, . . . measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site.” *Id.* at 23:53–55. The measurement site contact area may include windows 420–423 that “mimic or approximately mimic a configuration of, or even house, a plurality of detectors.” *Id.* at 23:61–24:8.

D. Illustrative Claim

Of the challenged claims, claims 1, 20, and 30 are independent. Claim 1 is illustrative and is reproduced below.

1. A physiological measurement system comprising:
 - [a] a physiological sensor device comprising:
 - [b] one or more emitters configured to emit light into tissue of a user;
 - [c] a first set of photodiodes, wherein:

[d] the first set of photodiodes comprises at least four photodiodes,

[e] the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream, and

[f] each of the photodiodes of the first set of photodiodes has a corresponding window that allows light to pass through to the photodiode;

[g] a second set of photodiodes, wherein:

[h] the second set of photodiodes comprises at least four photodiodes,

[i] the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream, and

[j] each of the photodiodes of the second set of photodiodes has a corresponding window that allows light to pass through to the photodiode;

[k] a wall that surrounds at least the first and second sets of photodiodes; and

[l] a cover comprising a protruding convex surface, wherein the protruding convex surface is above all of the photodiodes of the first and second sets of photodiodes, wherein at least a portion of the protruding convex surface is rigid, and wherein the cover is above the wall; and

[m] a handheld computing device in wireless communication with the physiological sensor device, wherein the handheld computing device comprises:

[n] one or more processors configured to wirelessly receive one or more signals from the physiological sensor device, the one or more signals responsive to at least a physiological parameter of the user;

[o] a touch-screen display configured to provide a user interface, wherein:

[p] the user interface is configured to display indicia responsive to measurements of the physiological parameter, and

[q] an orientation of the user interface is configurable responsive to a user input; and

[r] a storage device configured to at least temporarily store at least the measurements of the physiological parameter.

Ex. 1001, 45:2–49 (bracketed identifiers [a]–[r] added). Independent claim 20 includes limitations substantially similar to limitations [a]–[j] and [l]–[m] of claim 1. *Id.* at 47:9–36. Independent claim 30 includes limitations similar to limitations [a]–[r] of claim 1, and also includes additional recitations. *Id.* at 48:38–50:21 (reciting also a “substrate” and certain “preprocessing electronics”).

E. Applied References

Petitioner relies upon the following references:

Beyer, Jr., U.S. Patent No. 7,031,728 B2, filed Sept. 21, 2004, issued Apr. 18, 2006 (Ex. 1019, “Beyer”);

Ohsaki et al., U.S. Patent Application Publication No. 2001/0056243 A1, filed May 11, 2001, published December 27, 2001 (Ex. 1014, “Ohsaki”);

Aizawa, U.S. Patent Application Publication No. 2002/0188210 A1, filed May 23, 2002, published December 12, 2002 (Ex. 1006, “Aizawa”);

Y. Mendelson, et al., “Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter,” Proceedings of the 25th IEEE EMBS Annual International Conference, 3016–3019 (2003) (Ex. 1024, “Mendelson-2003”); and

Y. Mendelson et al., “A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring,” Proceedings of the 28th IEEE

EMBS Annual International Conference, 912–915 (2006) (Ex. 1010, “Mendelson-2006”).

Pet. 2. Petitioner also submits, *inter alia*, the Declaration of Thomas W. Kenny, Ph.D. (Ex. 1003), and the Second Declaration of Thomas W. Kenny (Ex. 1060). Patent Owner submits, *inter alia*, the Declaration of Vijay K. Madiseti, Ph.D. (Ex. 2004). The parties also provide deposition testimony from Dr. Kenny and Dr. Madiseti, including from this and other proceedings. *See* Exs. 1053–1054, 1056, 2006–2009, 2020, 2026, 2027.

F. Asserted Grounds

Petitioner asserts that claims 1–30 are unpatentable based upon the following grounds (Pet. 1–2):

Claims Challenged	35 U.S.C. §	References/Basis
1–18, 20, 22–30	103	Aizawa, Mendelson-2003, Ohsaki, Mendelson-2006
19, 21	103	Aizawa, Mendelson-2003, Ohsaki, Mendelson-2006, Beyer

II. DISCUSSION

A. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b) (2019). Petitioner submits that no claim term requires express construction. Pet. 3. Patent Owner submits that claim terms should be given their ordinary and customary meaning, consistent with the Specification. PO Resp. 9–10.

We agree that no claim terms require express construction. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of non-obviousness.¹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The

¹ Patent Owner does not present objective evidence of non-obviousness.

burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner identifies the appropriate level of skill in the art as that possessed by a person having “a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information.” Pet. 3 (citing Ex. 1003 ¶¶ 20–21). “Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.” *Id.*

Patent Owner makes several observations regarding Petitioner’s identified level of skill in the art but, “[f]or this proceeding, [Patent Owner] nonetheless applies Petitioner’s asserted level of skill.” PO Resp. 10 (citing Ex. 2004 ¶¶ 30–32).

We adopt Petitioner’s assessment as set forth above, which appears consistent with the level of skill reflected in the Specification and prior art.

D. Obviousness over the Combined Teachings of Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006

Petitioner contends that claims 1–18, 20, and 22–30 of the ’194 patent would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006. Pet. 12–72.

1. Overview of Aizawa (Ex. 1006)

Aizawa is a U.S. patent application publication titled “Pulse Wave Sensor and Pulse Rate Detector,” and discloses a pulse wave sensor that detects light output from a light emitting diode and reflected from a patient’s artery. Ex. 1006, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

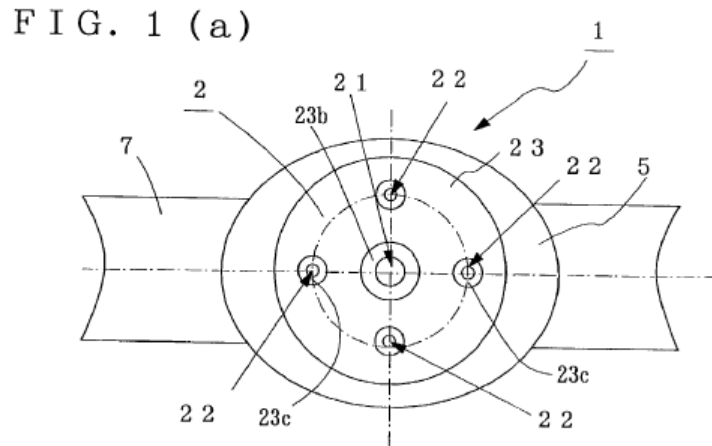


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode (“LED”) 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses that, “to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased.” *Id.* ¶ 32, Fig. 4(a). “The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22.” *Id.* ¶ 33.

Figure 1(b) of Aizawa is reproduced below.

F I G . 1 (b)

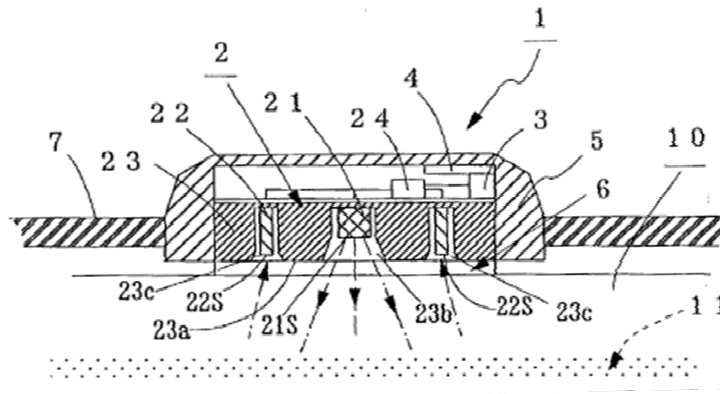


Figure 1(b) is a sectional view of the pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(b), pulse wave sensor 2 includes drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of photodetectors 22. *Id.* ¶ 23. Arithmetic circuit 3 computes a pulse rate from the detected pulse wave and transmitter 4 transmits the pulse rate data to an “unshown display.” *Id.* The pulse rate detector further includes outer casing 5 for storing pulse wave sensor 2, acrylic transparent plate 6 mounted to detection face 23a of holder 23, and attachment belt 7. *Id.* ¶ 23.

Aizawa discloses that LED 21 and photodetectors 22 “are stored in cavities 23b and 23c formed in the detection face 23a” of the pulse wave sensor. *Id.* ¶ 24. Detection face 23a “is a contact side between the holder 23 and a wrist 10, respectively, at positions where the light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back from the above detection face 23a.” *Id.* ¶ 24. Aizawa discloses that “a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 . . . in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side).” *Id.* ¶ 26. Furthermore, “the above belt 7 is fastened such that the acrylic

transparent plate 6 becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved.”

Id. ¶¶ 26, 34.

2. Overview of Mendelson-2003 (Ex. 1024)

Mendelson-2003 is a journal article titled “Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter,” which discusses a pulse oximeter sensor in which “battery longevity could be extended considerably by employing a wide annularly shaped photodetector ring configuration and performing SpO₂ measurements from the forehead region.” Ex. 1024, 3016.²

Mendelson-2003 explains that pulse oximetry uses sensors to monitor oxygen saturation (SpO₂), where the sensor typically includes light emitting diodes (LED) and a silicon photodetector (PD). *Id.* According to Mendelson-2003, when designing a pulse oximeter, it is important to offer “low power management without compromising signal quality.” *Id.* at 3017. “However, high brightness LEDs commonly used in pulse oximeters require[] relatively high current pulses, typically in the range between 100–200mA. Thus, minimizing the drive currents supplied to the LEDs would contribute considerably toward the overall power saving in the design of a more efficient pulse oximeter.” To achieve this goal, Mendelson-2003 discusses previous studies in which

the driving currents supplied to the LEDs . . . could be lowered significantly without compromising the quality of the

² Petitioner cites to the native page numbers appearing at the top of Exhibit 1024, rather than the added page numbering at the bottom of the pages. We follow Petitioner’s numbering scheme.

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[photoplethysmographic signal] by increasing the overall size of the PD Hence, by maximizing the light collected by the sensor, a very low power-consuming sensor could be developed, thereby extending the overall battery life of a pulse oximeter intended for telemedicine applications.

Id.

Mendelson-2003 discloses the prototype of such a sensor in Figure 1, which is reproduced below, and served as the basis for the studies evaluated in Mendelson-2003.

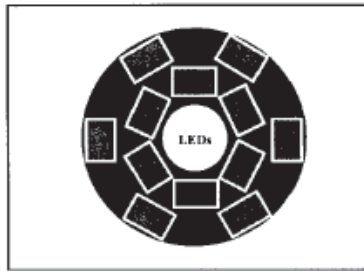


Figure 1 of Mendelson-2003 depicts a sensor configuration showing the relative positions of its PDs and LEDs. *Id.* As shown in Figure 1, “six PDs were positioned in a close inner-ring configuration at a radial distance of 6.0mm from the LEDs. The second set of six PDs spaced equally along an outer-ring, separated from the LEDs by a radius of 10.0mm.” *Id.* Mendelson-2003 also explains that “[e]ach cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter.” *Id.*

Mendelson-2003 reports the results of the studies as follows:

Despite the noticeable differences between the PPG signals measured from the wrist and forehead, the data plotted in Fig. 3 also revealed that considerable stronger PPGs could be obtained by widening the active area of the PD which helps to collect a bigger proportion of backscattered light intensity. The additional increase, however, depends on the area and relative position of the PD with respect to the LEDs. For example,

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utilizing the outer-ring configuration, the overall increase in the average amplitudes of the R and IR PPGs measured from the forehead region was 23% and 40%, respectively. Similarly, the same increase in PD area produced an increase in the PPG signals measured from the wrist, but with a proportional higher increase of 42% and 73%.

Id. at 3019.

3. Overview of Ohsaki (Ex. 1014)

Ohsaki is a U.S. patent application publication titled “Wristwatch-type Human Pulse Wave Sensor Attached on Back Side of User’s Wrist,” and discloses an optical sensor for detecting a pulse wave of a human body. Ex. 1014, code (54), ¶ 3. Figure 1 of Ohsaki is reproduced below.

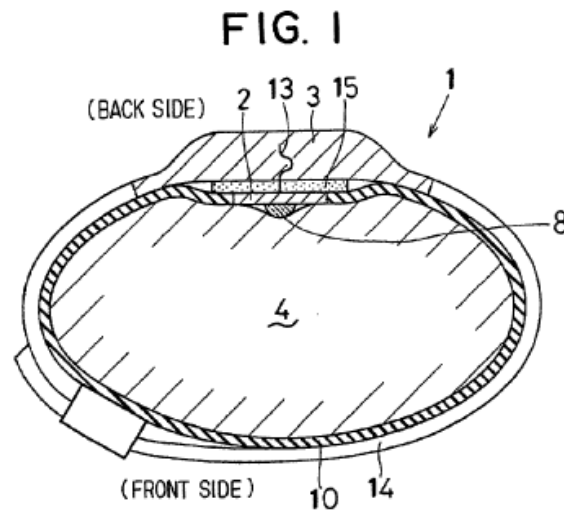


Figure 1 illustrates a cross-sectional view of pulse wave sensor 1 attached on the back side of user’s wrist 4. *Id.* ¶¶ 12, 16. Pulse wave sensor 1 includes detecting element 2 and sensor body 3. *Id.* ¶ 16.

Figure 2 of Ohsaki, reproduced below, illustrates further detail of detecting element 2.

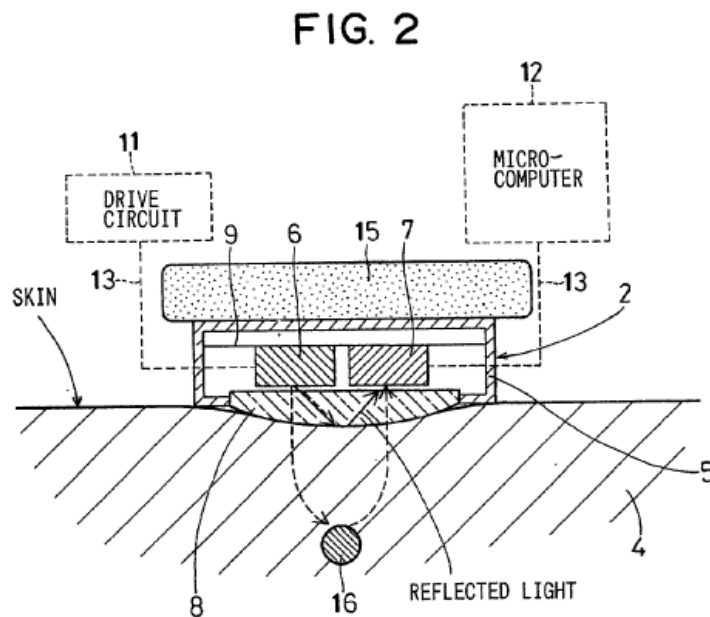


Figure 2 illustrates a mechanism for detecting a pulse wave. *Id.* ¶ 13. Detecting element 2 includes package 5, light emitting element 6, light receiving element 7, and translucent board 8. *Id.* ¶ 17. Light emitting element 6 and light receiving element 7 are arranged on circuit board 9 inside package 5. *Id.* ¶¶ 17, 19.

“[T]ranslucent board 8 is a glass board which is transparent to light, and attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8.” *Id.* ¶ 17. “[T]he convex surface of the translucent board 8 is in intimate contact with the surface of the user’s skin,” preventing detecting element 2 from slipping off the detecting position of the user’s wrist. *Id.* ¶ 25. By preventing the detecting element from moving, the convex surface suppresses “variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the

user's skin.” *Id.* Additionally, the convex surface prevents penetration by “noise such as disturbance light from the outside.” *Id.*

Sensor body 3 is connected to detecting element 2 by signal line 13. *Id.* ¶ 20. Signal line 13 connects detecting element 2 to drive circuit 11, microcomputer 12, and a monitor display (not shown). *Id.* Drive circuit 11 drives light emitting element 6 to emit light toward wrist 4. *Id.* Detecting element 2 receives reflected light which is used by microcomputer 12 to calculate pulse rate. *Id.* “The monitor display shows the calculated pulse rate.” *Id.*

4. Mendelson-2006 (Ex. 1016)

Mendelson-2006 is a journal article titled “A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring,” and discloses a wireless wearable pulse oximeter connected to a personal digital assistant (“PDA”). Ex. 1016, 1.

Figure 1 of Mendelson-2006 is reproduced below.



Figure 1 illustrates a sensor module attached to the skin (top), and a photograph of a disassembled sensor module and receiver module (bottom). The sensor module includes an optical transducer, a stack of round printed circuit boards, and a coin cell battery. *Id.* at 2.

Figure 2 of Mendelson-2006 is reproduced below.

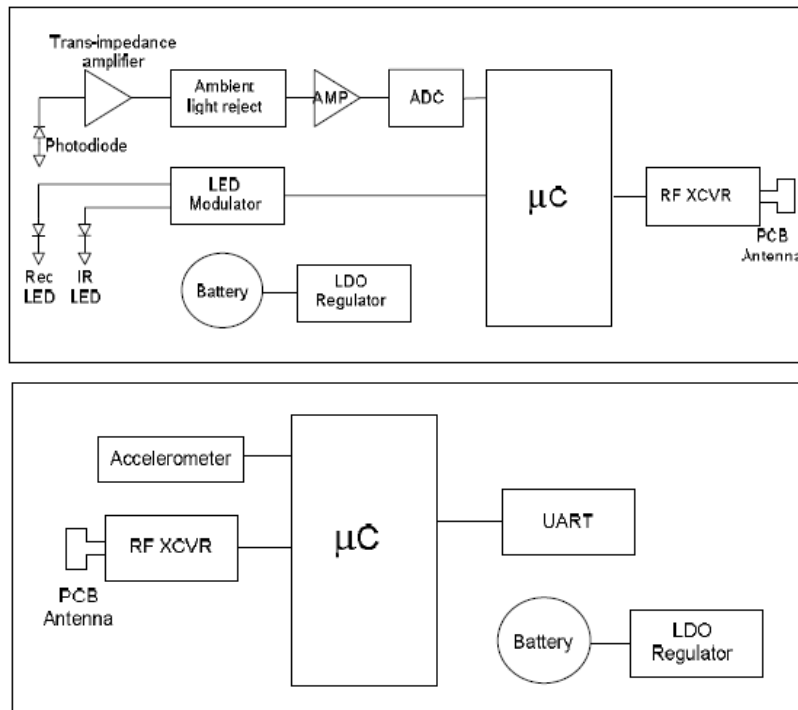


Figure 2 depicts a system block diagram of the wearable, wireless, pulse oximeter including the sensor module (top) and the receiver module (bottom). *Id.* The sensor module includes at least one light-emitting diode (“LED”), a photodetector, signal processing circuitry, an embedded microcontroller, and an RF transceiver. *Id.* at 1–2. Mendelson-2006 discloses that a concentric array of discrete photodetectors could be used to increase the amount of backscattered light detected by a reflectance type pulse oximeter sensor. *Id.* at 4. The receiver module includes an embedded microcontroller, an RF transceiver for communicating with the sensor module, and a wireless module for communicating with the PDA. *Id.* at 2.

As a PDA for use with the system, Mendelson-2006 discloses “the HP iPAQ h4150 PDA because it can support both 802.11b and Bluetooth™ wireless communication” and “has sufficient computational resources.” *Id.* at 3. Mendelson-2006 further discloses that

[t]he use of a PDA as a local terminal also provides a low-cost touch screen interface. The user-friendly touch screen of the PDA offers additional flexibility. It enables multiple controls to occupy the same physical space and the controls appear only when needed. Additionally, a touch screen reduces development cost and time, because no external hardware is required. . . . The PDA can also serve to temporarily store vital medical information received from the wearable unit.

Id.

The PDA is shown in Figure 3 of Mendelson-2006, reproduced below.



Figure 3 illustrates a sample PDA and its graphical user interface (“GUI”). *Id.* Mendelson-2006 explains that the GUI allows the user to interact with the wearable system. *Id.* “The GUI was configured to present the input and output information to the user and allows easy activation of various functions.” *Id.* “The GUI also displays the subject’s vital signs, activity

level, body orientation, and a scrollable PPG waveform that is transmitted by the wearable device.” *Id.* For example, the GUI displays numerical oxygen saturation (“SpO₂”) and heart rate (“HR”) values. *Id.*

5. Independent Claim 1

Petitioner contends that claim 1 would have been obvious over the combined teachings of Aizawa, Inokawa, Ohsaki, and Mendelson-2006. Pet. 30–54. Below, we set forth how the combination of prior art references teaches or suggests the claim limitations that are not disputed by the parties. For those limitations and reasons for combining the references that are disputed, we examine each of the parties’ contentions and then provide our analysis.

i. “A physiological measurement system comprising”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses the subject matter of the preamble.³ Pet. 30; *see, e.g.*, Ex. 1006 ¶ 2 (disclosing “a pulse wave sensor for detecting the pulse wave of a subject”).

ii. “[a] a physiological sensor device comprising”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses a physiological sensor device including a pulse rate detector. Pet. 30–31; *see, e.g.*, Ex. 1006 ¶ 23 (pulse wave sensor 2), Figs. 1(a)–(b).

³ Whether the preamble is limiting need not be resolved because Petitioner shows sufficiently that the preamble’s subject matter is satisfied by the prior art.

- iii. “[b] one or more emitters configured to emit light into tissue of a user”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses LED 21 that emits light into a user’s tissue. Pet. 31; see, e.g., Ex. 1006 ¶ 23 (“LED 21 . . . for emitting light having a wavelength of a near infrared range”), 27 (explaining that light is emitted toward the wrist), Fig. 1(b) (depicting emitter 21 facing user tissue 10).

- iv. “[c] a first set of photodiodes, wherein: [d] the first set of photodiodes comprises at least four photodiodes”
and
“[g] a second set of photodiodes, wherein: [h] the second set of photodiodes comprises at least four photodiodes”

Petitioner’s Undisputed Contentions

Petitioner contends that Aizawa discloses a first set of four photodiodes that are circularly arranged around a central emitter. Pet. 16 (citing, e.g., Ex. 1006 ¶ 23). Petitioner also contends that, in one embodiment, Aizawa discloses that eight or more detectors may be used to improve detection efficiency, but does not expressly teach a “second set of photodiodes,” as claimed. *Id.* at 17 (citing, e.g., Ex. 1006, Fig. 4(a)); see also Ex. 1003 ¶¶ 66–67.

Patent Owner does not dispute these contentions, and we agree with Petitioner. Aizawa discloses a set of “four phototransistors 22” that are disposed in a single ring around central emitter 21. Ex. 1006 ¶ 23, Figs. 1(a)–1(b). Aizawa also discloses that “the number of the photodetectors 22 may be increased” to further improve detection efficiency,

and depicts in Figure 4(a) an embodiment where eight photodetectors 22 are disposed in a single ring around central emitter 21. *Id.* ¶ 32.

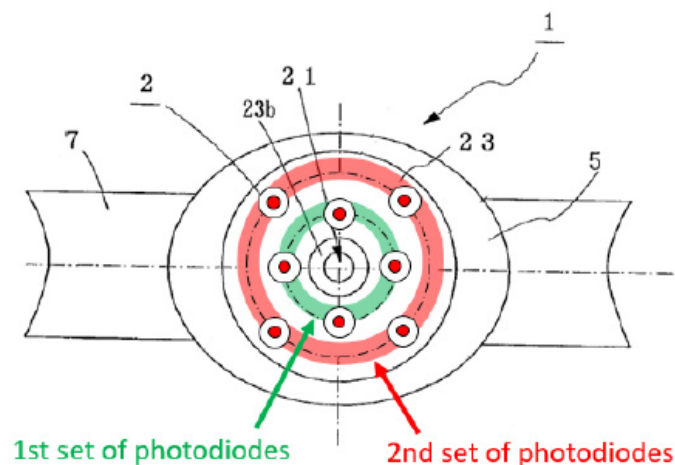
Also, according to Petitioner, Mendelson-2003 teaches a sensor that uses two rings of photodiodes, which improve light collection efficiency, permit use of lower brightness LEDs, and reduce power consumption. Pet. 18–19; *see also* Ex. 1003 ¶¶ 69–70.

Patent Owner does not dispute these contentions regarding what Mendelson-2003 discloses, and we agree with Petitioner. Mendelson-2003 teaches an experimental sensor in which “six PDs [(photodetectors)] were positioned in a close inner-ring configuration . . . [and a] second set of six PDs [were] spaced equally along an outer-ring.” Ex. 1024, 3017, Fig. 1 (depicting a prototype sensor with a near ring of photodetectors and a far ring of photodetectors). Based on experiments using the dual-ring sensor, as compared to sensors using only a near ring or only a far ring, Mendelson-2003 states that “considerabl[y] stronger PPGs [photoplethysmographic signals] could be obtained by widening the active area of the PD which helps to collect a bigger proportion of backscattered light intensity.” *Id.* at 3019, Fig. 3. Mendelson-2003 also states that, “by combining both PD sets to simulate a single large PD area, it is possible to further reduce the driving currents of the LEDs without compromising the amplitude or quality of the detected PPGs.” *Id.* at 3019, Fig. 4. Finally, Mendelson-2003 teaches that estimated battery life for the dual-ring sensor, as compared to sensors using only a near ring or only a far ring, “could be extended considerably.” *Id.* at 3019, Table 1 (battery life of 52.5 days for the dual-ring sensor, compared to 45.8 and 20.3 days for the near ring or far ring sensors, respectively).

Petitioner’s Disputed Contentions

In view of these teachings, Petitioner contends that a person of ordinary skill in the art would have found it obvious to modify Aizawa to include an additional ring of detectors, as taught by Mendelson-2003, (i.e., a “second set”) to “advance[e] Aizawa’s goal of improving detection efficiency through increased power savings.” Pet. 17–18 (citing, e.g., Ex. 1003 ¶ 68), 32–33 (citing, e.g., Ex. 1003 ¶¶ 90–91), 41–42 (citing, e.g., Ex. 1003 ¶¶ 100–101). According to Petitioner, “by using Mendelson-2003’s power-saving (and thus efficiency-enhancing) PD configuration, the power consumption of a wrist-based pulse sensing device as in Aizawa can be reduced through use of a less bright and, hence, lower power-consuming LED.” *Id.* at 19–20 (citing, e.g., Ex. 1003 ¶ 71).

Petitioner provides “[a]n example implementation of adding an additional ring of detectors to Aizawa, as per Mendelson-2003,” which is reproduced below.



Pet. 20 (citing, e.g., Ex. 1003 ¶ 72). Petitioner’s modified and annotated figure depicts Aizawa’s sensor with Aizawa’s first set of photodiodes (depicted as connected by a green ring) and modified to include a second set of photodiodes as taught by Mendelson-2003 (depicted as connected by a red ring). Pet. 20–21, 33, 41. Petitioner contends this would have been the

use of a known solution to improve similar systems in the same way, which “would have led to predictable results without significantly altering or hindering the functions performed by Aizawa’s sensor,” especially where Aizawa itself discloses adding extra detectors to improve light collection efficiency. *Id.* at 21–22 (citing, e.g., Ex. 1003 ¶ 74).

Patent Owner’s Arguments

Patent Owner’s arguments address limitations [c]–[e] and [g]–[i] together. *See* PO Resp. 55–66. As such, Patent Owner’s arguments, the parties’ Reply and Sur-reply briefing, and our analyses, are presented below in connection with limitations [e] and [i]. *See infra* § II.D.5.v.

- v. *“[e] the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream”
and
“[i] the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream”*

Petitioner’s Undisputed Contentions

Petitioner contends that a signal stream is sent from Aizawa’s set of photodetectors 23 to drive detection circuit 24, which amplifies the outputs of the photodetectors. Pet. 16 (citing, e.g., Ex. 1006 ¶ 23; Ex. 1003 ¶ 66).

Patent Owner does not dispute this contention, and we agree with Petitioner. Aizawa discloses that “drive detection circuit 24 [is] for detecting a pulse wave by amplifying the outputs of the photodetectors 22.” Ex. 1006 ¶ 23.

Petitioner additionally contends that Mendelson-2003 teaches that each set of photodiodes, i.e., its near ring and far ring, is wired in parallel,

thereby providing a distinct signal stream for each ring. Pet. 18, 34–35 (citing, e.g., Ex. 1024, 3017).

Patent Owner does not dispute this contention regarding what Mendelson-2003 discloses, and we agree with Petitioner. Mendelson-2003 teaches that “[e]ach cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter.” Ex. 1024, 3017.

Petitioner’s Disputed Contentions

In view of these teachings, Petitioner contends that a person of ordinary skill in the art “would have recognized and/or found it obvious that the first set of photodiodes [in the modified system of Aizawa and Mendelson-2003, *see supra* § II.D.5.iv] are connected to one another in parallel to provide a first signal stream in the manner claimed,” and “the photodiodes in the second/outer ring (i.e., second set of photodiodes) . . . are connected to one another in parallel to provide a second signal stream,” as taught by Mendelson-2003. Pet. 33–34, 42 (citing, e.g., Ex. 1003 ¶¶ 92–97, 102), 21 (citing, e.g., Ex. 1003 ¶ 73). Petitioner contends this “would have led to predictable results without significantly altering or hindering the functions performed by Aizawa’s sensor.” *Id.* at 21–22 (citing, e.g., Ex. 1003 ¶ 74).

According to Petitioner, this arrangement would have provided known benefits. Pet. 34–38. For example, Petitioner contends that a person of ordinary skill in the art “would have known that connecting multiple photodiodes together in parallel allows the current generated by the multiple photodiodes in [each] set/ring to be added to one another, thereby resulting in a larger total current akin to what would be generated from a single, large

detector.” *Id.* at 34. According to Petitioner, this was “a routine and conventional design choice.” *Id.* at 35. Further, “monitoring each signal stream (from each ring of detectors) separately allows the system to determine when the sensor device is so severely located that its position should be adjusted,” and can help detect motion artifacts. *Id.* at 35–36 (citing Ex. 1003 ¶ 95).

Petitioner also argues that a person of skill in the art would have known that “the photodiodes in the far ring (i.e., second set of photodiodes) would receive reflected light having a lower intensity than that received by the photodiodes in the near ring (i.e., first set of photodiodes) and would have been motivated and found it obvious to account for this discrepancy,” e.g., by “keep[ing] each ring separately wired and connected to its own amplifier . . . to thereby keep the magnitude of the current signals provided by each ring approximately the same before being combined and transmitted to the arithmetic circuit 3.” *Id.* at 36–38 (citing Ex. 1003 ¶¶ 96–97); *id.* at 42 (citing Ex. 1003 ¶ 102).

Patent Owner’s Arguments

Patent Owner disputes Petitioner’s contentions that it would have been obvious (1) to modify Aizawa to include a second set of at least four photodiodes, and (2) to wire the photodiodes of the first set in parallel to provide a first signal stream and to wire the photodiodes of the second set in parallel to provide a second signal stream. PO Resp. 55–66; PO Sur-reply 24–30.

First, Patent Owner argues this proposed modification changes Aizawa’s principle of operation. Specifically, Patent Owner claims that “Aizawa’s approach monitors different individual detector signals and

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calculates pulse rate based on each individual photodetector signal” and, in contrast to the proposed modification, “does not measure aggregated signals from detectors connected in parallel.” PO Resp. 57 (citing Ex. 1006 ¶¶ 7, 19, 23, 27–29, 32, 36; Ex. 2004 ¶ 102; Ex. 2026, 76:13–22, 79:22–80:3). According to Patent Owner, the proposed modification “eliminates Aizawa’s core feature—the ability to monitor pulse using the output of each individual detector, which Aizawa indicates avoids displacement problems.” *Id.* at 58–59 (citing, e.g., Ex. 2004 ¶¶ 104–105).

Second, Patent Owner argues this proposed modification would have resulted in increased power consumption. *Id.* at 59. According to Patent Owner, Mendelson-2003 states that its power savings is caused by “increasing the **number of detectors** and thus the detector area, not the two-ring structure.” *Id.* at 59–60 (citing Ex. 1024, 2; Ex. 2004 ¶ 106).

Moreover, Patent Owner argues that Aizawa already discloses a way to improve detection efficiency—by including eight detectors in a single ring. *Id.* at 60 (citing Ex. 1006 ¶ 32, Fig. 4A; Ex. 2004 ¶ 107). In light of this teaching, Patent Owner argues that adding a second ring is unfounded and unnecessary, especially where the second ring of detectors “would receive substantially lower light intensity requiring greater power consumption to utilize than additional detectors added to the ‘inner’ ring.” *Id.* at 60–62 (citing, e.g., Ex. 2004 ¶¶ 108–109; Ex. 2026, 55:7–17, 56:6–16, 59:14–60:7, 100:6–101:6, 102:5–17, 112:3–16). “Petitioner never explains why, given these straightforward options to increase signal strength, a [person of ordinary skill in the art] would instead add an entire new circle of detectors farther from the emitter.” *Id.* at 62.

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Third, Patent Owner argues that Mendelson-2003 provides only an experimental detector configuration, which would fail to provide the alleged benefits. Specifically, Patent Owner argues that Mendelson-2003 “uses its particular configuration for specific experiments comparing light intensity and LED drive currents for detectors arranged different distances from central emitters,” and “teaches no benefits for this arrangement in practice.” *Id.* at 62–63 (citing Ex. 1024, 4; Ex. 2004 ¶¶ 111–112). To the contrary, Patent Owner alleges that Mendelson-2003 actually prefers a single detector ring that outputs a single signal stream: “Mendelson 2003 explains it ‘combin[ed] both PD sets to simulate *a single* large PD area,’ and notes ‘battery longevity could be extended considerably by employing *a* wide annular PD,’ which has a single signal stream—not two different signal streams from two different parallel-connected rings.” *Id.* at 63 (citing, e.g., Ex. 2026. 87:8–88:1, 91:15–92:7).⁴ Thus, according to Patent Owner, even if a skilled artisan would have added a second ring of detectors to Aizawa, they “would not have kept the first and second ring of detectors *separate* or separately amplified the aggregated signals”; instead, they would have

⁴ Patent Owner also criticizes the Petition’s discussion of Exhibit 1025, U.S. Patent No. 6,801,799 (“Mendelson ’799”), which is not included in Petitioner’s identification of the asserted ground of unpatentability. PO Resp. 63–65; PO Sur-reply 29–30. We discern no error in Petitioner’s identification of Mendelson ’799. The nature of Petitioner’s reliance on Mendelson ’799 in support of this ground is explained clearly in the Petition, even if Mendelson ’799 is not listed as an additional reference in the identification of the ground. Thus, the Petition complies with 35 U.S.C. § 312(a)(3) (stating an IPR petition must “identif[y], in writing and with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge”).

“combin[ed] both PD sets to simulate *a single* large PD area,” where “battery longevity could be extended considerably by employing a wide annular PD.” *Id.* at 66 (quoting Ex. 1024, 4; citing Ex. 2004 ¶ 116).

Finally, Patent Owner argues that the proposed combination “introduces signal processing problems requiring a *further* redesign for Aizawa’s sensor” to include a second amplifier to account for signals of different strengths between the near and far rings. *Id.* at 65–66 (citing Ex. 2004 ¶ 115). Patent Owner alleges this demonstrates that a skilled artisan would not have added a second ring of detectors, as proposed, but instead would have increased the number of detectors in Aizawa’s single ring. *Id.* at 66.

Petitioner’s Reply

Petitioner replies that Patent Owner mischaracterizes Aizawa’s principle of operation. Pet. Reply 32–34. Specifically, Petitioner contends that Aizawa’s detector ring is connected in parallel, or at least that a person of ordinary skill in the art would have recognized that parallel connection would have been a known implementation detail, which allows a signal to be detected even if one of the multiple sensors is displaced on the user. *Id.* at 33 (citing Ex. 1003 ¶¶ 93–94; Ex. 1060 ¶ 62; Ex. 2026, 72:3–9). Moreover, Petitioner argues that Aizawa lacks any disclosure of individually monitoring signals from each photodetector. *Id.* at 34.

Petitioner reiterates its position that adding a second ring would collect a bigger portion of backscattered light, and would have motivated the proposed combination. *Id.* at 35 (citing, e.g., Ex. 1060 ¶¶ 65–66). Petitioner also disputes that such a modification would increase power, noting that it is the emitters, not the detectors, that consume most power in the system. *Id.*

at 36 (citing, e.g., Ex. 1060 ¶ 67). Moreover, Petitioner contends that by widening the detection area with a second ring, the system would capture additional light which would allow a lower brightness, and lower power, emitter to be used. *Id.*

Petitioner disputes Patent Owner's characterization of Mendelson-2003 as purely experimental, and alleges that Mendelson-2003 makes clear that employing two rings outputting two signal streams is equivalent to employing a wider single ring of detectors, and provides associated benefits. *Id.* at 36–38 (citing, e.g., Ex. 1060 ¶ 70).

Patent Owner's Sur-reply

Patent Owner reiterates its position that Aizawa concerns individual monitoring, which Patent Owner alleges is a “key feature of Aizawa's sensor,” in order to avoid problems associated with sensor displacement. PO Sur-reply 24–26. Patent Owner also reiterates its positions that the proposed modified sensor would consume more power, and that Aizawa's disclosed embodiment with eight detectors in a single ring would have been preferred. *Id.* at 26–29.

Analysis

We have considered the parties' arguments and cited evidence, and we are persuaded by Petitioner's contentions. As discussed above, Aizawa discloses a sensor with a first set of four phototransistors 22 as claimed, which are disposed in a single ring around central emitter 21. Ex. 1006 ¶ 23, Figs. 1(a)–1(b). Mendelson-2003 teaches a sensor with a dual-ring configuration, where a first inner ring includes six photodetectors, and a second outer ring includes an additional six photodetectors. Ex. 1024, 3017, Fig. 1. Mendelson-2003 also states that by using this dual-ring

configuration to simulate a wide photodetector area, stronger signals could be obtained, drive currents could be reduced, and battery life could be extended. *Id.* at 3019, Fig. 3, Fig. 4.

In light of these explicit teachings, we are persuaded by Petitioner’s contention that a person of ordinary skill in the art would have found it obvious to include a second set of detectors in Aizawa’s sensor, as taught by Mendelson-2003, to realize the benefits taught by Mendelson-2003, i.e., stronger signals with reduced power consumption. Pet. 17–18, 41–42. We credit Dr. Kenny’s testimony that this would have been the use of a known solution—a sensor with dual detector rings as taught by Mendelson-2003—to improve similar systems—Aizawa’s sensor with one detector ring—in the same way, which “would have led to predictable results without significantly altering or hindering the functions performed by Aizawa’s sensor,” especially where Aizawa itself discloses adding extra detectors to improve light collection efficiency. Ex. 1003 ¶ 74.

We also credit Dr. Kenny’s testimony that, as taught by Mendelson-2003, it would have been obvious to connect the photodetectors of each set in parallel to provide first and second signal streams, respectively, and that this would have led to predictable results. Ex. 1003 ¶ 74 (predictable), 93–94 (first set), 102 (second set). Indeed, the two rings taught by Mendelson-2003 are disclosed as being “wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter.” Ex. 1024, 3017. Dr. Kenny explains numerous advantages associated the parallel connections taught by Mendelson-2003, such as monitoring for displacement, accounting for motion artifacts, and

compensating for the relative decrease in light that reaches the outer ring, which cannot be achieved with a single signal stream. Ex. 1003 ¶¶ 95–97.

We have considered Patent Owner’s arguments but find them to be misplaced. First, we do not agree that Aizawa discloses the ability to individually monitor individual detectors as a “key feature” (PO Resp. 56; PO Sur-reply 25) of its sensor. We discern no persuasive support for this position in Aizawa. Aizawa does not discuss individual monitoring at all, at least not clearly, and does not discuss individual monitoring as a solution to sensor displacement. Rather, Aizawa explains that its sensor includes four photodetectors 22 and that “reflected light is detected by the plurality of photodetectors 22.” Ex. 1006 ¶¶ 23, 27. Aizawa also explains that its sensor includes a “drive detection circuit for detecting a pulse wave by amplifying the outputs of the photodetectors 22.” *Id.* ¶ 23. These disclosures indicate that Aizawa does not monitor each photodetector 22 individually to ascertain the pulse wave but, rather, utilizes “the outputs” of *all* of the photodetectors together.

This understanding is consistent with Aizawa’s disclosure of sensor displacement. As Patent Owner correctly notes, Aizawa recognizes a problem with sensor displacement, in which “no output signal can be obtained” if the sensor’s detectors are placed away from an artery. *Id.* ¶ 7. Aizawa solves this problem by avoiding a “linear[]” detector arrangement, such that “[e]ven when the attachment position of the sensor is dislocated, a pulse wave can be detected accurately.” *Id.* ¶ 9. Indeed, Aizawa is clear that, in its preferred embodiment, it is the disposition of photodetectors 22 in “a circle concentric to the light emitting diode 21” that enables accurate

pulse detection even when the sensor is dislocated. *Id.* ¶ 27. Aizawa does not discuss individual monitoring in relation to sensor dislocation.

We have examined Patent Owner’s alleged support for the importance of individual monitoring and find it unavailing. *See, e.g.*, PO Resp. 57 (citing Ex. 1006 ¶¶ 7, 19, 23, 27–29, 32, 36; Ex. 2004 ¶ 102; Ex. 2026, 76:13–22, 79:22–80:3). Patent Owner identifies Figure 3, which depicts a “diagram of a pulse wave which is the output of *a photodetector*.” Ex. 1006 ¶¶ 19 (emphasis added), 28 (“the above photodetector 22”). Patent Owner seems to place importance on the use of the article “a” or “the” photodetector, in the singular. PO Resp. 57; PO Sur-reply 24. However, we discern no significance in the singular use. In discussing this Figure, Aizawa does not discuss monitoring an individual photodetector, or describe that as a “key feature”; instead, Aizawa explains that drive detection circuit 24 amplifies the detected pulse wave and transmits it to arithmetic circuit 3, which compares it to a threshold value to calculate a pulse rate. Ex. 1006 ¶ 28. We discern that this discussion of how the circuits process a signal from “a” (or “the”) photodetector is merely exemplary of the process; Patent Owner has not pointed to any persuasive support for its position that this somehow indicates a “key feature” of Aizawa is individual monitoring. As noted above, Aizawa plainly discloses that it is the signals from *the plurality* of photodetectors that are used to determine a pulse wave. *Id.* ¶¶ 23, 27. Nothing in Figure 3 or paragraph 28 clearly contradicts that disclosure.

We have considered the cited testimony of Dr. Madisetti, which Patent Owner relies upon as support for its position, but we find it unavailing as well. Dr. Madisetti’s testimony includes the same citations presented by Patent Owner, none of which demonstrates individual

monitoring. Ex. 2004 ¶ 102. Thus, we determine this testimony to be conclusory and entitled to little weight.

We do recognize, as did Dr. Kenny during his deposition, that Aizawa does not provide extensive discussion of the algorithms through which Aizawa determines a pulse wave. *See, e.g.*, Ex. 2026, 80:8–18 (“It doesn’t describe the algorithm in detail. It just says amplifies the signals from the detectors and then performs whatever function takes place inside the arithmetic circuit which I think computes the number of times the signal crosses the threshold value to calculate the pulse rate, but there’s not a clearly described precise algorithm for what goes on. It’s left for one of ordinary skill in the art to process the waveforms and, and count the crossings of the threshold and determine the pulse rate.”). Nonetheless, we decline Patent Owner’s invitation to import into Aizawa’s disclosure a “key feature” of individual monitoring that is not identified by Aizawa with any reasonable clarity. Again, as noted above, Dr. Madisetti provides no further support for the conclusory position advanced by Patent Owner.

By contrast, we credit Dr. Kenny’s testimony, which is consistent with Aizawa’s express disclosure of detecting a pulse wave from “the plurality of photodetectors” (Ex. 1006 ¶ 27), that:

connecting multiple photodetectors together in parallel allows the current generated by the multiple photodetectors to be added to one another, which would subsequently ensure that even if one of multiple sensors connected in parallel were to be displaced so as to receive no signal, the fact that all the sensors are connected in parallel such that their signals are summed means that a signal will still be detected, in accordance with Aizawa’s objective.

Ex. 1060 ¶ 62. Moreover, we agree with Dr. Kenny that “there is no disclosure anywhere in Aizawa to suggest that it is even capable of

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somehow monitoring the signals of each photodetector, and there is certainly no need to do so if its sensors are connected in parallel.” *Id.* Thus, considering the express disclosure of Aizawa and the competing testimony of the parties’ experts, we credit that of Dr. Kenny.

Patent Owner’s second argument—that the proposed modification would have resulted in increased power consumption—is plainly contradicted by Mendelson-2003’s disclosure. Table 1 of Mendelson-2003 is reproduced below.

Table 1. Comparison of estimated battery life for different PD configurations. Values based on forehead measurements for a typical 220mAh coin size battery.

PD CONFIGURATION	BATTERY LIFE [Days]
Near	45.8
Far	20.3
Near+Far	52.5

Table 1 includes three rows, each associating a different photodetector configuration with an estimated battery life. Ex. 1024, 3019. The table indicates that a configuration consisting of only a near ring of photodetectors results in 45.8 days of battery life; a configuration consisting of only a far ring of photodetectors results in 20.3 days of battery life; and a configuration consisting of both a near ring and a far ring of photodetectors results in 52.5 days of battery life. *Id.* In describing this table, Mendelson-2003 states, “the considerable differences in the estimated power consumptions clearly points out the practical advantage gained by using a reflection sensor comprising a large ring-shaped PD area to perform SpO₂ measurements,” which in this case, was realized by the combination of a near and far ring of detectors, akin to the modification proposed by Petitioner. *Id.* Thus, we do not agree with Patent Owner’s argument that power consumption would

increase if a second ring of detectors were added to Aizawa's sensor; Mendelson-2003 plainly suggests the opposite and supports Petitioner's contention that the proposed modification would result in a power savings over a single ring.

We also do not agree with the argument that a person of ordinary skill in the art would not make the proposed modification because Aizawa already discloses a way to improve detection efficiency, e.g., by including more detectors in a single ring. PO Resp. 60 (citing Ex. 1006 ¶ 32, Fig. 4A; Ex. 2004 ¶ 107). Aizawa explains that the photodetector arrangement of its single-ring preferred embodiment "is not limited" and suggests, "[f]or example," that "the number of photodetectors 22 may be increased." Ex. 1006 ¶ 32. Aizawa does not limit the increase in photodetectors to being included in only the existing single ring of detectors, i.e., the first set. Nothing in this disclosure teaches against adding a second set, as proposed by Petitioner for the well-supported reasons identified in Mendelson-2003 and further discussed by Dr. Kenny.

Patent Owner's third argument—that Mendelson-2003 is experimental and would not provide the alleged benefits—likewise fails. Patent Owner's suggestion that Mendelson-2003 teaches using a single large, wide detector ring that outputs a single signal stream is unfounded. The analysis provided in Mendelson-2003 explicitly compares a dual-ring arrangement to both a single near ring and a single far ring. *See, e.g.*, Ex. 1024, Fig. 3, Fig. 4, Table 1 (all comparing near, far, and near + far arrangements). Mendelson-2003 explains that the dual-ring arrangement "simulate[s] a single large PD area" and realizes benefits in LED power requirements. *Id.* at 3019. That

Mendelson-2003 *simulates* a single ring by using two discrete rings demonstrates the fallacy of Patent Owner’s argument.

Finally, we disagree with Patent Owner’s argument that a person of ordinary skill in the art would not have made the proposed combination because it “introduces signal processing problems requiring a *further* redesign for Aizawa’s sensor” to include a second amplifier to account for signals of different strengths between the near and far rings. PO Resp. 65–66. A person of ordinary skill in the art must be presumed to understand something about the art beyond what is disclosed in the references. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). After all, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Neither Patent Owner nor Dr. Madisetti asserts that adding a second amplifier would be beyond the level of skill in the art or would introduce any specific problems, beyond its mere addition. We credit Dr. Kenny’s testimony that a person of ordinary skill would have recognized that, in order to account for the disparate currents generated by the two rings, the rings would be separately wired with separate amplifiers (Ex. 1003 ¶ 97) and that this would have been a routine and conventional design choice, within the level of ordinary skill in the art (*id.* ¶ 94).

For the foregoing reasons, we are persuaded by Petitioner’s contentions.

- vi. “[f] each of the photodiodes of the first set of photodiodes has a corresponding window that allows light to pass through to the photodiode”
and
“[j] each of the photodiodes of the second set of

photodiodes has a corresponding window that allows light to pass through to the photodiode”

The cited evidence supports Petitioner’s undisputed contention that Aizawa teaches windows corresponding to each detector of Aizawa, i.e., “tapered cavities that provide an opening for each of the detectors (e.g., each of the photodiodes of the first set of photodiodes) and that serve to increase, for instance, the concentration of light collected by the detectors, thereby increasing the signal to noise ratio,” and that a person of ordinary skill in the art also would have provided such windows for the second set of photodiodes, suggested by the combination with Mendelson-2003. Pet. 38–40, 42; *see, e.g.*, Ex. 1006 ¶¶ 23 (“four phototransistors 22”), 24 (“stored in cavities” and “set back from . . . detection face 23a”), Figs. 1(a)–1(b) (depicting cavities 23c housing detectors 22); Ex. 1003 ¶¶ 98–99, 103.

vii. *“[k] a wall that surrounds at least the first and second sets of photodiodes”*

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses holder 23, which includes a wall that surrounds the photodetectors, as well as other elements. Pet. 42–44; *see, e.g.*, Ex. 1006 ¶ 23 (“holder 23 for storing . . . light emitting diode 21 and the photodetectors 22”), Fig. 1(b) (depicting holder 23 surrounding the detector).

viii. *“[l] a cover comprising a protruding convex surface, wherein the protruding convex surface is above all of the photodiodes of the first and second sets of photodiodes, wherein at least a portion of the*

protruding convex surface is rigid, and wherein the cover is above the wall”

Petitioner’s Undisputed Contentions

Petitioner contends that Aizawa “teaches a light permeable cover in the form of an acrylic transparent plate 6 . . . that is mounted at the detection face 23a” of the sensor, i.e., above Aizawa’s photodetectors, to provide “improved adhesion between the detector and the wrist to ‘further improv[e] the detection efficiency of a pulse wave.’” Pet. 9–10 (citing Ex. 1006 ¶ 30, Fig. 1(b); Ex. 1003 ¶¶ 53–54). Patent Owner does not dispute this contention, and we agree with Petitioner. Aizawa discloses that “acrylic transparent plate 6 is provided on the detection face 23a of the holder 23 to improve adhesion to the wrist 10.” Ex. 1014 ¶ 34, Fig. 1(b) (depicting transparent plate 6 between sensor 2 and wrist 10).

Petitioner also contends that Ohsaki teaches a wrist-worn sensor that includes a “translucent board” having a convex surface that contacts the user’s skin. Pet. 12–13, 22–23. Patent Owner does not dispute this contention, and we agree with Petitioner. Ohsaki discloses that sensor 1 includes detecting element 2 and sensor body 3, and is “worn on the back side of the user’s wrist.” Ex. 1014 ¶ 16. Ohsaki discloses that detecting element 2 includes package 5 and “translucent board 8[,which] is a glass board which is transparent to light, [and is] attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8.” *Id.* ¶ 17. As seen in Ohsaki’s Figure 2, translucent board 8 has a protruding convex surface, and is located above all of the detectors. *Id.* ¶ 17 (“The translucent board 8 is . . . attached to the opening of the package 5.”), Fig. 2.

Petitioner also contends that Ohsaki's Figure 2 depicts the user's tissue conforming to the shape of the convex surface of the cover, such that the convex surface would have been "rigid." Pet. 45–46. Patent Owner does not dispute this contention, and we agree with Petitioner. Ohsaki's Figure 2 depicts the user's tissue 4 conforming to the shape of the protruding convex surface when the sensor is worn by the user. Ex. 1014 ¶ 17 ("The translucent board 8 is a glass board."), Fig. 2; *see, e.g.*, Ex. 1003 ¶¶ 107–108.

Petitioner's Disputed Contentions

Petitioner further contends that a person of ordinary skill in the art would have found it obvious "to modify the sensor's flat cover [in Aizawa] . . . to include a lens/protrusion . . . similar to Ohsaki's translucent board 8, so as to [1] improve adhesion between the user's wrist and the sensor's surface, [2] improve detection efficiency, and [3] protect the elements within sensor housing." Pet. 24–25 (citing, *e.g.*, Ex. 1003 ¶ 78; Ex. 1014 ¶ 25), 44 (citing, *e.g.*, Ex. 1003 ¶ 105). Petitioner contends that Ohsaki's convex surface is in "intimate contact" with the user's tissue, which prevents slippage of the sensor and increases signal strength because "variation of the amount of the reflected light . . . that reaches the light receiving element 7 is suppressed" and because "disturbance light from the outside" is prevented from penetrating board 8, as compared to a sensor with a flat surface. *Id.* at 22–24 (citing, *e.g.*, Ex. 1003 ¶¶ 76–77; quoting Ex. 1014 ¶¶ 15, 17, 25).

Petitioner contends this modification would have been "nothing more than the use of a known technique to improve similar devices in the same way," *i.e.*, "simply improving Aizawa-Mendelson-2003's transparent plate 6

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that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor.” Pet. 25 (citing Ex. 1003 ¶ 79). Further according to Petitioner, “the elements of the combined system would each perform functions they had been known to perform prior to the combination—Aizawa-Mendelson-2003's transparent plate 6 would remain in the same position, performing the same function, but with a convex surface as taught by Ohsaki.” *Id.* at 26.

To illustrate its proposed modification, Petitioner includes two annotated versions of Aizawa's Figure 1(b), both of which are reproduced below. Pet. 25.

FIG. 1 (b)

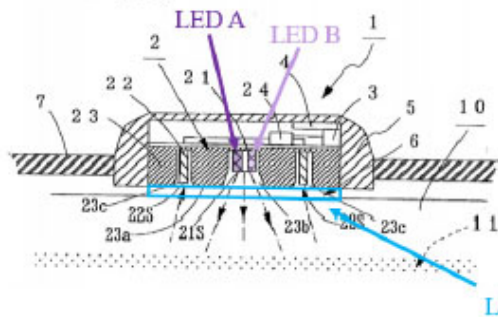
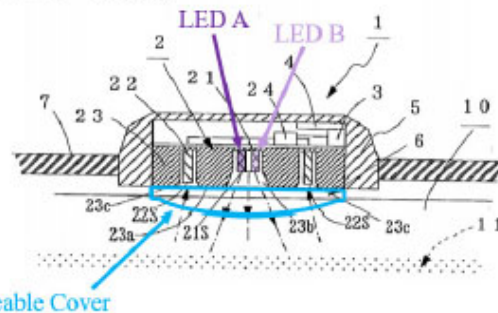


FIG. 1 (b)



Petitioner's annotated figure on the left depicts Aizawa's sensor, modified to include LED B (*see supra* Section II.D.5.iii) and with a flat “light permeable cover” (illustrated with blue outline); Petitioner's annotated figure on the right depicts Aizawa's sensor, again modified to include LED B (*see supra* Section II.D.5.iii) and with a convex “light permeable cover” (also illustrated with blue outline). Petitioner contends that, in the combination, the convex surface is above the wall provided by the holder. Pet. 45 (citing, e.g., Ex. 1003 ¶ 106).

Petitioner also identifies Japanese Patent Application 2006-296564 to Inokawa (Ex. 1007 (Japanese language); Ex. 1008 (English language

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translation))), which Petitioner contends “provides an additional motivation and rationale . . . to modify Aizawa to include a cover comprising a protruding convex surface.” Pet. 26. According to Petitioner, Inokawa teaches a convex lens that “increase[s] the light-gathering ability of the LED.” *Id.* (citing Ex. 1008 ¶ 15, Fig. 2). Petitioner contends that, in view of Inokawa, a person of ordinary skill in the art would have understood how to implement Ohsaki’s convex surface in Aizawa. *Id.* at 27–28 (citing Ex. 1003 ¶¶ 82–83).

Patent Owner’s Arguments

Patent Owner argues that a person of ordinary skill in the art would not have been motivated to modify Aizawa’s sensor to include Ohsaki’s convex cover. PO Resp. 24–55;⁵ PO Sur-reply 3–23.

First, Patent Owner argues that the proposed modification “fundamentally changes Ohsaki’s structure and eliminates the longitudinal shape that gives Ohsaki’s translucent board the ability to prevent slipping.” PO Resp. 25. This argument is premised on Patent Owner’s contention that Ohsaki’s convex cover must be rectangular, with the cover’s long direction

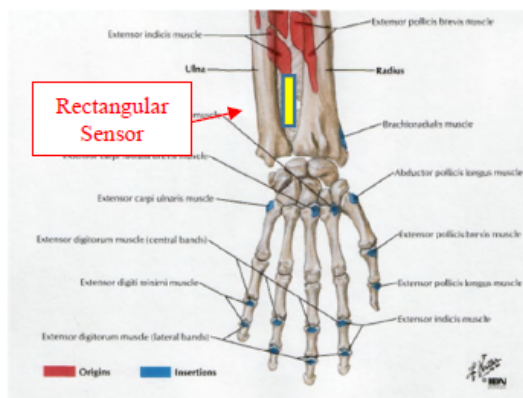
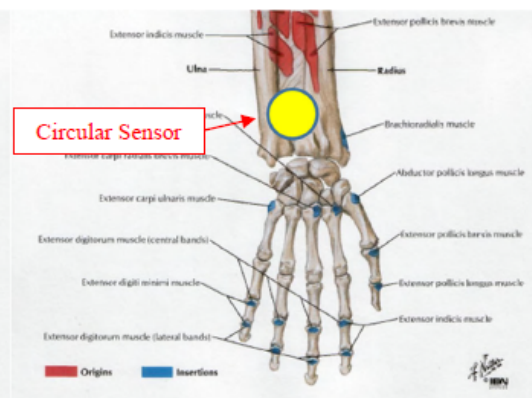
⁵ As an initial matter, Patent Owner observes that Petitioner “[r]eli[es] on a non-ground reference, Inokawa,” as providing the rationale for the proposed modification of Aizawa in view of Ohsaki, and as providing implementation details of the combination. PO Resp. 24 (citing Pet. 26–27); *id.* at 46–47, 52–55. We discern no error in Petitioner’s identification of Inokawa. The nature of Petitioner’s reliance on Inokawa in support of this ground is explained clearly in the Petition, even if Inokawa is not listed as an additional reference in the identification of the ground. Thus, the Petition complies with 35 U.S.C. § 312(a)(3) (stating an IPR petition must “identif[y], in writing and with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge”).

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aligned with the length of the user's forearm, to avoid interacting with bones in the wrist and forearm. *Id.* at 26–28 (citing, e.g., Ex. 2004 ¶¶ 53–57; Ex. 1014 ¶¶ 6, 19, 23, 24). According to Patent Owner, Ohsaki teaches that “aligning the sensor's longitudinal direction with the *circumferential* direction of the user's arm undesirably results in ‘a tendency [for Ohsaki's sensor] to slip off.’” *Id.* at 28 (citing Ex. 1014 ¶ 19).

Thus, Patent Owner contends that Petitioner's proposed modification would “chang[e] Ohsaki's longitudinal detecting element and rectangular board into a circular shape[, which] would eliminate the advantages discussed above” because a circular shape “cannot be placed in *any longitudinal* direction and thus cannot coincide with the longitudinal direction of the user's wrist.” *Id.* at 28 (citing Ex. 2004 ¶¶ 57–58). Patent Owner presents annotated Figures depicting what it contends is Ohsaki's disclosed sensor placement as compared to that of the proposed modification, reproduced below. *Id.* at 29.

Ohsaki's Longitudinal TeachingsPetitioner's Proposed Combination

Patent Owner's annotated Figure on the left depicts a rectangular sensor placed between a user's radius and ulna, while Patent Owner's annotated Figure on the right depicts a circular sensor placed across a user's radius and

ulna. Based on these annotations, Patent Owner argues that the proposed “circular shape would press on the user’s arm in all directions and thus cannot avoid the undesirable interaction with the user’s bone structure,” such that a skilled artisan “would have understood such a change would eliminate Ohsaki’s benefit of preventing slipping.” *Id.* at 31 (citing, e.g., Ex. 2004 ¶¶ 57–58), 31 (citing Ex. 2004 ¶¶ 55–62).⁶

Second, Patent Owner argues that Ohsaki requires its sensor be placed on the back of the user’s wrist to achieve any benefits, but that such a location would have been unsuitable for Aizawa’s sensor. PO Resp. 34. Specifically, Patent Owner argues that Aizawa’s sensor must be worn on the palm side of the wrist, close to radial and ulnar arteries, which is the side opposite from where Ohsaki’s sensor is worn. *Id.* at 35–40 (citing, e.g., Ex. 2004 ¶¶ 67–74). According to Patent Owner, Ohsaki teaches that the sensor’s convex surface has a tendency to slip when placed on the palm side of the wrist, i.e., in the location taught by Aizawa. *Id.* at 40–43 (citing, e.g., Ex. 1014 ¶¶ 19, 23, 24; Ex. 2004 ¶¶ 75–81). Thus, Patent Owner argues that a person of ordinary skill in the art “would not have been motivated to use Ohsaki’s longitudinal board—designed to be worn on the **back side** of a user’s wrist—with Aizawa’s **palm-side** sensor.” *Id.* at 43. Similarly, Patent Owner argues that Aizawa teaches away from the proposed modification because Aizawa teaches that its flat acrylic plate improves adhesion on the

⁶ Patent Owner further argues, “[t]o the extent Petitioner contends a [person of ordinary skill in the art] would use Ohsaki’s **rectangular** board on Aizawa’s circular sensor . . . this argument is unsupported and incorrect.” PO Resp. 31. We do not read the Petition as making such a contention. We understand Petitioner to propose, in essence, changing Aizawa’s circular *flat* cover into a circular *convex* cover. *See, e.g.*, Pet. 25.

palm side of the wrist, while Ohsaki teaches that its convex board “has a tendency to slip” on the palm side of the wrist. *Id.* at 43–46 (citing, e.g., Ex. 2004 ¶¶ 82–85).

Third, Patent Owner argues that a person of ordinary skill in the art would not have placed Ohsaki’s convex cover over Aizawa’s peripheral detectors because the convex cover would condense light toward the center and away from Aizawa’s detectors, which would decrease signal strength. PO Resp. 46–54 (citing, e.g., Ex. 2004 ¶¶ 86–97). Patent Owner also contends that Petitioner and Dr. Kenny admitted as much in a related proceeding. *Id.* at 47–48 (citing, e.g., Ex. 2019, 45; Ex. 2020, 69–70). Patent Owner also relies on Figure 14B of the ’194 patent to support its position. *Id.* at 48–49 (citing Ex. 1001, 36:3–6, 36:13–15). Additionally, Patent Owner argues that its position is also supported by Inokawa, which also uses a convex lens to direct light toward the center but, in Inokawa’s structure, the light is directed from peripheral emitters toward a central detector. *Id.* at 52–54 (citing, e.g., Ex. 1008 ¶¶ 15, 58). In light of the foregoing, Patent Owner argues that a person of ordinary skill in the art would have understood that the proposed modification would have decreased signal strength by directing light away from Aizawa’s peripheral detectors. *Id.* at 49–51.

Fourth and finally, Patent Owner argues that a person of ordinary skill in the art “would have understood that Aizawa’s *flat* plate would provide better protection than a convex surface” because it “would be less prone to scratches.” *Id.* at 54–55 (citing Ex. 1008 ¶ 106; Ex. 2004 ¶¶ 98–99).

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Petitioner's Reply

Concerning Patent Owner's first and second arguments, Petitioner responds that Ohsaki does not disclose the shape of its protrusion, other than its convexity as shown in Figures 1 and 2, nor does Ohsaki require a rectangular shape or placement on the back of the wrist in order to achieve the disclosed benefits. Pet. Reply 13–20 (citing, e.g., Ex. 1060 ¶¶ 18–30). Moreover, Petitioner asserts that “even if Ohsaki's translucent board 8 were understood to be rectangular, obviousness does not require ‘bodily incorporation’ of features from one reference into another”; rather, a person of ordinary skill in the art “would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits” taught by Ohsaki. *Id.* at 16 (citing, e.g., Ex. 1060 ¶ 23). Similarly, regarding the location of the sensor, Petitioner asserts,

[E]ven assuming for the sake of argument that a [person of ordinary skill in the art] would have understood Aizawa's sensor as being limited to placement on the backside of the wrist, and would have understood Ohsaki's sensor's “tendency to slip” when arranged on the front side as informing consideration of Ohsaki's teachings with respect to Aizawa, that **would have further motivated** the [person of ordinary skill in the art] to implement a light permeable convex cover in Aizawa's sensor, to improve detection efficiency of that sensor when placed on the palm side.

Id. at 18 (citing, e.g., Ex. 1060 ¶ 27). In other words, Ohsaki's disclosure that a convex surface suppresses variation in reflected light would have motivated an artisan to add such a surface to Aizawa to improve detection efficiency of that sensor when placed on the palm side. *Id.* at 18–20. Moreover, Petitioner replies that the proposed convex surface “would provide an additional adhesive effect that would reduce the tendency of that

plate to slip, among other things since it is well-understood that physically digging into the skin with a protrusion provides an additional adhesive effect.” *Id.* at 20 (citing Ex. 1060 ¶ 30).

Concerning Patent Owner’s third argument, Petitioner responds that Patent Owner’s argument about a convex cover directing light to the center is belied by Ohsaki itself, which uses a convex cover over a non-centrally located detector. *Id.* (citing Ex. 1060 ¶ 31); *id.* at 30–31. According to Petitioner, Ohsaki demonstrates that even if a convex cover decreased signal strength (which it disputes), the additional benefit of reduced slippage would have been recognized by a skilled artisan. *Id.*

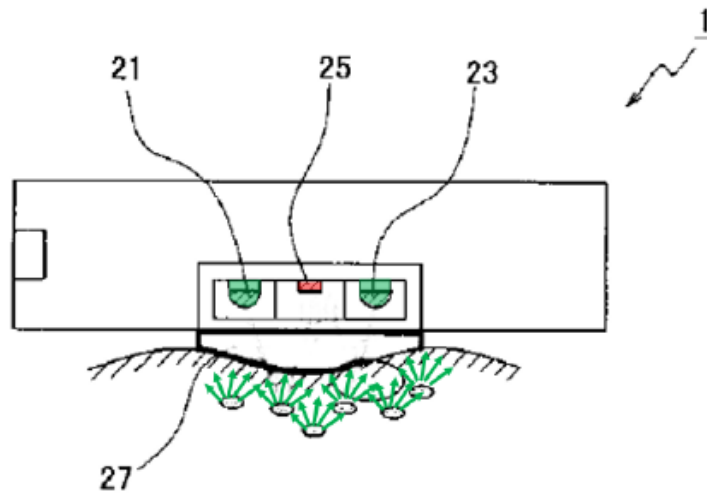
Further, Petitioner responds that adding a convex cover to Aizawa’s sensor would not decrease signal strength but, instead, “would improve Aizawa’s signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa’s photodetectors than would have with a flat cover” because such a cover improves light concentration across the entire lens and does not direct it only towards the center. *Id.* at 21–22 (citing, e.g., Ex. 1060 ¶¶ 31–34).

Petitioner asserts that Patent Owner and Dr. Madisetti “ignore[] the well-known optical *principle of reversibility*,” by which “a ray going from P to S will trace the same route as one from S to P” such that “rays that are not completely absorbed by user tissue will propagate in a reversible manner.” Pet. Reply 22 (quoting Ex. 1061, 92; citing, e.g., Ex. 1061, 87–92; Ex. 1062, 106–111; Ex. 1060 ¶ 35). When applied to Aizawa’s sensor, Petitioner contends that any condensing benefit achieved by a convex cover would thus direct emitted light toward Aizawa’s peripheral detectors. *Id.* at 23–25 (citing, e.g., Ex. 1060 ¶¶ 35–44). Petitioner explains that this principle of

reversibility is recognized in Aizawa. *Id.* at 25 (citing, e.g., Ex. 1060 ¶¶ 41–44; citing Ex. 1006 ¶ 33).

Petitioner also asserts that Patent Owner and Dr. Madisetti overlook the fact that light rays reflected by body tissue will be scattered and diffuse and will approach the detectors “from various random directions and angles.” Pet. Reply 29 (citing, e.g., Ex. 1023, 52, 86, 90; Ex. 1056, 803; Ex. 1060 ¶¶ 46–49; Ex. 2006, 163:12–164:2). This scattered and diffuse light, according to Petitioner, means that Ohsaki’s convex cover cannot focus light to the center of the sensor device, as Patent Owner argues. *Id.* at 26. Instead, due to the random nature of this scattered light, Petitioner asserts that a person of ordinary skill in the art would have understood that “Ohsaki’s convex cover provides a slight refracting effect, such that light rays that otherwise would have missed the detection area are instead directed toward that area as they pass through the interface provided by the cover.” *Id.* (citing, e.g., Ex. 1060 ¶¶ 48–49). Petitioner applies this understanding to Aizawa, and asserts that using a cover with a convex protrusion in Aizawa would “enable backscattered light to be detected within a circular active detection area surrounding” a central light source. *Id.*

Petitioner relies upon the following illustration of this alleged effect. Pet. Reply 29–30 (citing Ex. 1060 ¶¶ 54–55).



APPLE-1061, 141 (annotated)

The above illustration depicts backscattered light reflecting off user tissue and toward a convex board from various angles. *Id.* at 29. According to Petitioner, “[t]his pattern of incoming light cannot be focused by a convex lens towards any single location,” and, instead, “light rays that otherwise would have missed the active detection area are instead directed toward that area as they pass through the interface provided by the convex cover.” *Id.* at 29–30.

Finally, Petitioner dismisses Patent Owner’s reliance on Figure 14B of the ’194 patent because it “is not an accurate representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., parallel to one another), and each light ray’s path is perpendicular to the detecting surface.” Pet. Reply 28–29 (citing, e.g., Ex. 1060 ¶¶ 51–53).

Concerning Patent Owner’s fourth argument, Petitioner responds that even if a flat surface might be less prone to scratching, that possible disadvantage would have been weighed against the “known advantages of applying Ohsaki’s teachings,” and would not negate a motivation to

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combine. *Id.* at 32 (citing, e.g., Ex. 1060 ¶ 60). Moreover, Petitioner argues that “by choosing a suitable material of the protrusion to be scratch-resistant, it would have been obvious for a [person of ordinary skill in the art] to achieve both benefits (light gathering and scratch-resistance) at once.” *Id.*

Patent Owner’s Sur-reply

Concerning Patent Owner’s first and second arguments, Patent Owner reiterates its position that Ohsaki’s purported benefits attach only to a sensor with a rectangular convex surface that is located on the back of the wrist, and that “even small changes in its sensor’s orientation or body location result in ‘a tendency to slip.’” PO Sur-reply 3–14, 6.

Concerning Patent Owner’s third argument, Patent Owner asserts that Petitioner’s Reply improperly presents several new theories as compared with the Petition. *Id.* at 16 (regarding reversibility), 19 (regarding refraction).

Patent Owner argues that Dr. Kenny and Petitioner have not overcome their admissions that a convex lens directs light toward the center. *Id.* at 15. Moreover, Patent Owner argues that Petitioner’s discussion of the principle of reversibility is “irrelevant” because “Petitioner never explains how the principle of reversibility could apply to such ‘random’ scattered and absorbed light” as is present when light interacts with user tissue. *Id.* at 16–17. The random nature of backscattered light, in Patent Owner’s view, “hardly supports Petitioner’s argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed,” and is irrelevant to the central issue presented here of “whether changing Aizawa’s flat surface to a convex surface results in more light on Aizawa’s peripherally located detectors.” *Id.* at 17–18.

Patent Owner also asserts that Petitioner mischaracterizes Patent Owner's position, which is not that a cover with a convex protrusion "focuses *all* light to a single point" at the center of the sensor as Petitioner characterizes it. PO Sur-reply 19. Patent Owner's position, rather, is that Petitioner has not shown that a person of ordinary skill in the art "would have been motivated to change Aizawa's flat surface to a convex surface to improve signal strength." *Id.* In Patent Owner's view, by arguing that the convex cover provides only a "*slight* refracting effect," Petitioner undermines its contention that providing such a cover would have improved detection efficiency. *Id.* at 20.

Moreover, Patent Owner argues that Petitioner's theory regarding the "slight refracting effect" of a convex protrusion is "unavailing because it fails to consider the greater *decrease* in light at the detectors due to light redirection to a *more* central location." *Id.* at 20. According to Patent Owner, any light redirected from the sensor's edge could not make up for the loss of signal strength from light redirected away from the detectors and toward the center. *Id.*

Concerning Patent Owner's fourth argument, Patent Owner argues that Petitioner does not dispute Patent Owner's position that a flat cover would be less prone to scratches and offers "*no* plausible advantages for its asserted combination." *Id.* at 23. Moreover, Patent Owner argues that "[t]he risk of scratches undermines Petitioner's argument that a [person of ordinary skill in the art] would have been motivated to add a convex cover to 'protect the elements within the sensor housing.'" *Id.*

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Analysis

As noted above, Petitioner provides three rationales to support its contention that a person of ordinary skill in the art would have modified Aizawa's flat cover to include a protruding convex surface, such as that taught by Ohsaki, to (1) improve adhesion between the sensor and the user's tissue, (2) improve detection efficiency, and (3) protect the elements within the sensor housing. Pet. 24–25. We conclude all three rationales are supported by the evidence, as follows.

Rationales 1 and 2

The evidence of record persuades us that adding a convex protruding surface, such as that taught by Ohsaki, to Aizawa's cover would have improved adhesion between the sensor and the user's skin, which would have increased the signal strength of the sensor. Ohsaki teaches as much:

[T]he convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby *it is prevented that the detecting element 2 slips off* the detecting position of the user's wrist 4. If the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4 as shown in Fig. 4B. However, in the case that the translucent board 8 has a convex surface like the present embodiment, the *variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8.* Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

Ex. 1014 ¶ 25 (emphases added); *see also id.* ¶ 27 (“stably fixed”).

We credit Dr. Kenny's testimony that a person of ordinary skill in the art would have been motivated by such teachings to apply a cover with a

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convex surface to Aizawa to improve that similar device in the same way and to yield predictable results, i.e., to resist movement of the sensor on the user's wrist. *See, e.g.*, Ex. 1003 ¶¶ 76 (“[T]his contact between the convex surface and the user's skin is said to prevent slippage, which increases the strength of the signals obtainable by Ohsaki's sensor.”), 78–79. We also credit Dr. Kenny's testimony that, in light of these teachings, a person of ordinary skill in the art would have made such a modification to improve the pulse sensor's ability to emit light into, and detect light reflected from, the user's wrist, to generate an improved pulse signal. Ex. 1003 ¶¶ 76–78; Ex. 1060 ¶¶ 13, 29.

Indeed, Ohsaki expressly compares the performance of a wrist-worn pulse wave sensor depending on whether translucent board 8 is convex or flat, and concludes the convex surface results in improved performance over the flat surface, especially when the user is moving. Ex. 1014, Figs. 4A–4B, ¶¶ 15, 25 (stating that with “a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4,” and with “a convex surface like the present embodiment, the variation of the amount of the reflected light” collected by the sensor “is suppressed”). Ohsaki also states that, with a convex surface, “[i]t is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8.” *Id.* ¶ 25.

We also credit Dr. Kenny's testimony that the proposed modification would have been within the skill level of an ordinary artisan. For example, Dr. Kenny testifies:

[A person of ordinary skill in the art] would have combined the teachings of Aizawa-Mendelson-2003 and Ohsaki as doing so would have amounted to nothing more than the use

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of a known technique to improve similar devices in the same way. For instance, [a person of ordinary skill in the art] would have recognized that incorporating Ohsaki's convex surface is simply improving Aizawa-Mendelson-2003's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor. Furthermore, the elements of the combined system would each perform similar functions they had been known to perform prior to the combination. That is, Aizawa-Mendelson-2003's transparent plate 6 would remain in the same position, performing the same function, but with a convex surface as taught by Ohsaki.

Ex. 1003 ¶ 79. In light of Ohsaki's express disclosure of the benefits of a convex cover, we credit Dr. Kenny's testimony that a person of ordinary skill in the art would have been motivated to modify Aizawa as proposed, and would have had a reasonable expectation of success in doing so.

We next address Patent Owner's first through third arguments, each of which implicates Petitioner's first and second asserted rationales of improved adhesion and detection efficiency.

Patent Owner's first argument is premised on the notion that Ohsaki's benefits only can be realized with a rectangular convex surface, because such a shape is required to avoid interacting with bones on the back of the user's forearm. PO Resp. 25–34. We disagree. Ohsaki does not disclose the shape of its convex cover, much less require it be rectangular. In fact, Ohsaki is silent as to the shape of the convex surface. Ohsaki discloses that sensor 1 includes detecting element 2, which includes package 5 within which the sensor components are located. Ex. 1014 ¶ 17. Ohsaki's convex surface is located on board 8, which is “attached to the opening of the package 5.” *Id.* Ohsaki provides no further discussion regarding the shape of board 8 or its convex protrusion.

We disagree with Patent Owner’s suggestion that the shape of the convex surface can be inferred to be rectangular from Ohsaki’s Figures 1 and 2. PO Resp. 18–20. Ohsaki does not indicate that these figures are drawn to scale, or reflect precise dimensions or shapes of the convex surface. *See, e.g.*, Ex. 1014 ¶ 13 (“schematic diagram”); Pet. Reply 14–15; *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000) (“[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”).

To be clear, Ohsaki describes the shape of *detecting element 2* as rectangular: “[T]he length of the detecting element from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side.” Ex. 1014 ¶ 19. Ohsaki also describes that detecting element 2 is aligned longitudinally with the user’s forearm: “[I]t is desirable that the detecting element 2 is arranged so that its longitudinal direction agrees with the longitudinal direction of the user’s arm,” to avoid slipping off. *Id.*; *see also id.* ¶ 9 (“The light emitting element and the light receiving element are arranged in the longitudinal direction of the user’s arm.”).

In light of this disclosed rectangular shape of detecting element 2, it is certainly possible that Ohsaki’s convex surface may be similarly shaped. But, it may not be. Contrary to Patent Owner’s argument, Ohsaki neither describes nor requires detecting element 2 to have the same shape as the convex surface of board 8. *Accord* Pet. Reply. 13–14. We have considered the testimony of both Dr. Kenny and Dr. Madisetti on this point. Ex. 1060 ¶¶ 10, 12, 18–23; Ex. 2004 ¶¶ 36–39 (relying on Ohsaki’s Figures 1–2 to support the opinion that the convex surface is rectangular). Dr. Madisetti’s

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reliance on the dimensions of Ohsaki's figures is unpersuasive. *Hockerson-Halberstadt*, 222 F.3d at 956. We credit Dr. Kenny's testimony that Ohsaki does not describe its convex surface as rectangular, because this testimony is most consistent with Ohsaki's disclosure.

Further, Patent Owner suggests that the convex surface *must be* rectangular, in order to avoid interacting with bones in the user's forearm. PO Resp. 26–28; PO Sur-reply 10 (“[A] POSITA would have understood Ohsaki's convex board must *also* have a longitudinal shape oriented up-and-down the watch-side of the user's wrist/forearm.”). Although Ohsaki recognizes that interaction with these bones can cause problems, (*see* Ex. 1014 ¶¶ 6, 19), we do not agree that the *only way* to avoid these bones is by aligning a rectangular cover with the longitudinal direction of the user's forearm. For example, in the annotated Figures provided by Patent Owner, *see* PO Resp. 29, we discern that the circular sensor that purports to depict the proposed modification would *also* avoid the bones in the forearm if it were slightly smaller. Patent Owner provides no persuasive explanation to justify the dimensions it provides in this annotated figure, or to demonstrate that such a large sensor would have been required. Indeed, we discern that it would have been within the level of skill of an ordinary artisan to appropriately size a modified sensor to avoid these well-known anatomical obstacles. *See, e.g.*, Ex. 1060 ¶ 25 (“The gap between the ulna and radius bones at the forearm is even greater than the gap between bones at the wrist, which is already wide enough to easily accommodate a range of sensor sizes and shapes, including circular shapes.”). “A person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421.

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After all, an artisan must be presumed to know something about the art apart from what the references disclose. *See In re Jacoby*, 309 F.2d at 516.

Finally, we do not agree with Patent Owner's position that Ohsaki's advantages apply only to rectangular convex surfaces. As discussed, Patent Owner has not shown that Ohsaki's convex surface is rectangular at all. Moreover, even if Ohsaki's convex surface is rectangular, when discussing the benefits associated with a convex cover, Ohsaki does not limit those benefits to a cover of any particular shape. Instead, Ohsaki explains that "detecting element 2 is arranged on the user's wrist 4 so that the convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby it is prevented that the detecting element 2 slips off the detecting position of the user's wrist 4." Ex. 1014 ¶ 25; Ex. 1060 ¶¶ 10 ("Ohsaki does not limit its benefits to a rectangular sensor applied to a particular body location, and a [person of ordinary skill in the art] would not have understood those benefits as being so limited."), 12. Thus, we agree with Petitioner that Ohsaki's teaching of a convex surface would have motivated a person of ordinary skill in the art to add such a surface to Aizawa's circular-shaped sensor, to improve adhesion as taught by Ohsaki. Nothing in Ohsaki's disclosure limits such a benefit to a specific shape of the convex surface. Ex. 1060 ¶¶ 10–23.

Moreover, Ohsaki contrasts the ability to properly receive reflected light with a convex surface as compared to a flat surface and notes that,

in the case that the translucent board 8 has a convex surface . . . the variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8.

Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

Ex. 1014 ¶ 25; Ex. 1060 ¶¶ 12–13. Again, we agree with Petitioner that Ohsaki's teaching of a convex surface would have motivated a person of ordinary skill in the art to add such a surface to Aizawa's sensor, to improve signal strength, as taught by Ohsaki. Again, nothing in Ohsaki's disclosure limits such a benefit to the shape of the convex surface.

Accordingly, we do not agree that Ohsaki's disclosed advantages attach only to a rectangular convex surface, or would have been inapplicable to the proposed combination of Aizawa and Ohsaki.

We have considered Patent Owner's second argument, that Ohsaki's benefits are realized only when the sensor and convex surface are placed on the back of the user's wrist, which is the opposite side of the wrist taught by Aizawa. PO Resp. 34–46. We do not agree. As an initial matter, Petitioner does not propose bodily incorporating the references; Petitioner simply proposes adding a convex cover to Aizawa's sensor, without discussing where Aizawa's sensor is used. *See, e.g.*, Pet. 24–25. In other words, Petitioner's proposed modification does not dictate any particular placement, whether on the palm side or back side of the wrist.

To be sure, Ohsaki's Figures 3A–3B compare the performance of detecting element 2, including its translucent board 8 having a convex protrusion, and show better performance when the element is attached to the back side of the wrist versus the front side of the wrist, when the user is in motion. *See* Ex. 1014 ¶¶ 23–24, Figs. 3A–3B. However, we do not agree that these figures support Dr. Madisetti's conclusion that “Ohsaki indicates a convex surface only prevents slipping on the back (i.e., watch) side of the wrist in a specific orientation, but tends to slip when used in different

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locations or orientations” such as the palm side of the wrist—particularly in comparison to a flat surface such as Aizawa’s. Ex. 2004 ¶¶ 67–81. Instead, Ohsaki acknowledges that, even when the detecting element is located “on the front [palm] side of the user’s wrist 4, *the pulse wave can be detected well* if the user is at rest.” Ex. 1014 ¶ 23 (emphasis added). Thus, Ohsaki discloses that, in at least some circumstances, a convex surface located on the front of the user’s wrist achieves benefits. *Id.* Notably, the claims are not limited to detection during movement or exercise.

We credit, instead, Dr. Kenny’s testimony that a person of ordinary skill in the art would have understood from Ohsaki that a convex protrusion will help prevent slippage, even in the context of Aizawa’s sensor. *See* Ex. 1060 ¶¶ 10–11, 15–16, 24–30. Dr. Kenny acknowledges that

certain locations present anatomical features that provide for easy measurement of large reflected light signals and other locations present anatomical features that reduce the amplitude of the reflected light signals. Because of this, a [person of ordinary skill in the art] would be motivated to search for features from other references that can provide improved adhesion, improved light gathering, reduced leakage of light from external sources, and protection of the elements within the system in order to successfully detect a pulse wave signal from many locations.

Id. ¶ 16. We credit Dr. Kenny’s testimony that, in light of Ohsaki’s teaching of a convex protrusion in “intimate contact with the surface of the user’s skin,” a skilled artisan would have understood that such a surface “would have increased adhesion and reduced slippage of Aizawa’s sensor when placed on either side of a user’s wrist or forearm, and additionally would have provided associated improvements in signal quality.” *Id.* ¶ 29.

Dr. Madisetti testifies that “[b]ased on Aizawa’s teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki’s

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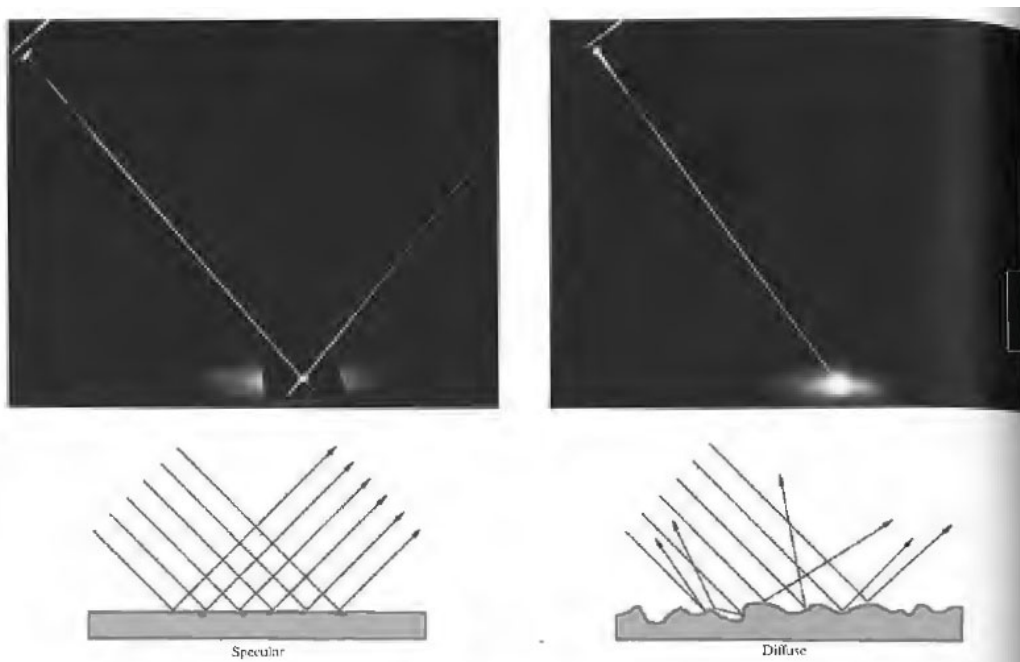
teaching that a convex surface tends to slip on the palm side of the wrist, a [person of ordinary skill in the art] would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa's flat adhesive plate 'to include a lens/protrusion . . . similar to Ohsaki's translucent board' would not 'improve adhesion.'" Ex. 2004 ¶ 85. We disagree with this reading of Aizawa. It is true that Aizawa's plate 6 is illustrated as having a flat surface (Ex. 1006, Fig. 1(b)), and that Aizawa states the plate "improve[s] adhesion" (*id.* ¶ 13). Aizawa further states: "the above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10," and "[t]hereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved." *Id.* ¶ 26. These disclosures, however, indicate the improved adhesion is provided by the acrylic material of plate 6, not the shape of the surface of the plate, which is never specifically addressed. *Id.* ¶¶ 30, 34 ("Since the acrylic transparent plate 6 is provided . . . adhesion between the pulse rate detector 1 and the wrist 10 can be improved . . ."). Aizawa does not associate this benefit of improved adhesion with the surface shape of the plate, but rather, with the existence of an acrylic plate to begin with. Thus, there is no teaching away from using a convex surface to improve the adhesion of Aizawa's detector to the user's wrist.

We have considered Patent Owner's third argument that a convex cover would condense light away from Aizawa's peripheral detectors, which Patent Owner alleges would decrease signal strength. PO Resp. 46–54. We disagree.

There appears to be no dispute that when emitted light passes through user tissue, the light diffuses and scatters as it travels. *See, e.g.,* Pet. Reply 25 ("[R]eflectance-type sensors work by detecting light that has been

‘partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.’ A [person of ordinary skill in the art] would have understood that light that backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles.”) (quoting Ex. 1023, 86); PO Sur-reply 16–17 (“Even Petitioner admits, however, that tissue randomly scatters and absorbs light rays, which would cause forward and reverse light paths to be unpredictable and very likely different.”).

The light thus travels at random angles and directions, and no longer travels in a collimated and perpendicular manner. Exhibit 1061,⁷ Figure 4.12, illustrates the difference between diffuse and collimated light, and is reproduced below:



This figure provides at left a photograph and an illustration showing incoming collimated light reflecting from a smooth surface, and at right a photograph and an illustration of incoming collimated light reflecting from a

⁷ Eugene Hecht, *Optics* (2nd ed. 1990).

rough surface. *See* Ex. 1061, 87–88 (original page numbers). The smooth surface provides specular reflection, in which the reflected light rays are collimated like the incoming light rays. *See id.* The rough surface provides diffuse reflection, in which the reflected light rays travel in random directions. *See id.*; *see also* Ex. 1060 ¶¶ 38–39 (discussing Ex. 1061, Figure 4.12), 46 (“A [person of ordinary skill in the art] would have understood that light that backscatters from the measurement site (after diffusing through tissue) reaches the active detection area from many random directions and angles.”).

Dr. Kenny testifies that Aizawa’s sensor “detect[s] light that has been ‘partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.’” Ex. 1060 ¶ 53 (quoting Ex. 1023, 86). Dr. Kenny further opines that a convex cover, when added to Aizawa’s sensor with multiple detectors symmetrically arranged about a central light source, “allows light rays that otherwise would have missed the detection area to instead be directed toward that area as they pass through the interface provided by the cover,” thus increasing the light-gathering ability of Aizawa’s sensor. *Id.* ¶ 49.

By contrast Dr. Madisetti testifies that “a convex ‘lens/protrusion’ would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors” because it condenses light towards the center of the sensor and away from the peripheral detectors. Ex. 2004 ¶¶ 86–87, 90. We have considered this testimony, however, Dr. Madisetti’s opinions largely are premised upon the behavior of collimated and perpendicular light as depicted in Figure 14B of the challenged patent. *See id.* ¶ 89. Dr. Madisetti does not explain how light

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would behave when approaching the sensor from various angles, as it would after being reflected by tissue. *Id.* ¶¶ 87–90; *see also id.* ¶¶ 91–97 (addressing motivation and also failing to discuss diffuse, scattered light). In other words, even if Patent Owner is correct that the '194 patent's Figure 14B depicts light condensing toward the center, this is not dispositive to the proposed modification, because light reflected by a user's tissue is scattered and random, and is not collimated and perpendicular as shown in Figure 14B. Ex. 1001, Fig. 14B.

Patent Owner and Dr. Madisetti argue that “Petitioner and Dr. Kenny both [previously admitted] that a convex cover condenses light towards the center of the sensor and away from the periphery,” in a different petition filed against a related patent, i.e., in IPR2020-01520. PO Resp. 47–48; Ex. 2004 ¶ 87. The cited portions of the Petition and Dr. Kenny's declaration from IPR2020-01520 discuss a decrease in the “mean path length” of a ray of light when it travels through a convex lens rather than through a flat surface. *See, e.g.*, Ex. 2020 ¶¶ 118–120. We do not agree that this discussion is inconsistent with Dr. Kenny's testimony here that, where light is reflected to the detectors at various random angles and directions, more light will reach Aizawa's symmetrically disposed detectors when travelling through the convex surface than would be reached without such a surface, because light that might have otherwise missed the detectors now will be captured. *See, e.g.*, Ex. 1060 ¶¶ 31 (“[A] cover featuring a convex protrusion would improve Aizawa's signal-to- noise ratio by causing more light backscattered from tissue to strike Aizawa's photodetectors than would have with a flat cover.”), 34 (“improves ‘light concentration at pretty much *all of the locations under the curvature of the lens*’”), 46 (“A [person of

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ordinary skill in the art] would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles.”), 49 (“[L]ight rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover.”); *see generally id.* ¶¶ 31–59. We do not discern that the convergence of a single ray of light toward the center, as discussed in IPR2020-01520, speaks to the aggregate effect on *all* light that travels through the convex surface.

We additionally do not agree with Patent Owner’s argument that Petitioner’s Reply presents new theories that should have been first presented in the Petition, to afford Patent Owner an adequate opportunity to respond. The Petition proposed a specific modification of Aizawa to include a convex protrusion in the cover, for the purpose of, *inter alia*, increasing the light gathering ability of Aizawa’s device. *See* Pet. 24–25. Patent Owner’s Response then challenged that contention, with several arguments that Petitioner’s proposed convex protrusion would not operate in the way the Petition alleges it would operate. *See* PO Resp. 46–54. This opened the door for Petitioner to provide, in the Reply, arguments and evidence attempting to rebut the contentions in the Patent Owner Response. *See* PTAB Consolidated Trial Practice Guide (Nov. 2019) (“Consolidated Guide”),⁸ 73 (“A party also may submit rebuttal evidence in support of its reply.”). This is what Petitioner did here. The Reply does not change Petitioner’s theory for obviousness; rather, the Reply presents more argument and evidence in support of the same theory for obviousness presented in the Petition. *Compare* Pet. 22–28, *with* Reply 20–31.

⁸ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

Rationale 3

Petitioner further contends that a person of ordinary skill in the art would have recognized that a cover with a protruding convex surface, such as that taught by Ohsaki, would “protect the elements within the sensor housing” of Aizawa. Pet. 24–25. We are persuaded that adding a convex cover, such as that taught by Ohsaki, would also protect the sensor’s internal components in a manner similar to Aizawa’s flat acrylic plate. Ex. 1003 ¶ 105; Ex. 1060 ¶ 60; *see also* Ex. 1008 ¶ 15 (noting that a cover “protect[s] the LED or PD”).

We disagree with Patent Owner’s fourth argument that a person of ordinary skill in the art would not have modified Aizawa as proposed because a convex cover would be prone to scratches and because other alternatives existed. Patent Owner does not explain how the potential presence of scratches on a convex cover would preclude that cover’s ability to, nonetheless, protect the internal sensor components in Aizawa, as Petitioner proposes. That a convex cover may be more prone to scratches than Aizawa’s flat cover is one of numerous tradeoffs that a person of ordinary skill in the art would consider in determining whether the benefits of increased adhesion, signal strength, and protection outweigh the potential for a scratched cover. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Moreover, as Petitioner notes, and Patent Owner does not dispute, a scratch resistant material could be employed in fabricating the cover. Pet. Reply 32; PO Sur-reply 23. The record does not support the premise that the possibility of scratches alone would have dissuaded a person of ordinary skill in the art from the proposed modification, to achieve the benefits identified by Petitioner.

For the foregoing reasons, we are persuaded by Petitioner's contentions.

- ix. “[m] a handheld computing device in wireless communication with the physiological sensor device, wherein the handheld computing device comprises”

Petitioner's Contentions

Petitioner contends Aizawa teaches a sensor device that uploads data to an external display, but notes that Aizawa “is silent about how such data transmission would be implemented.” Pet. 28 (citing Ex. 1006 ¶¶ 15, 23, 35; Ex. 1003 ¶ 84). Petitioner contends that Mendelson-2006 teaches that a body-worn sensor wirelessly communicates data to a body-worn receiver module, and the receiver module then wirelessly communicates data to a handheld PDA. *Id.* at 14, 28–29, 47.⁹ Petitioner additionally contends that a person of ordinary skill in the art would have “found it obvious and straightforward to further modify Aizawa-Mendelson-2003-Ohsaki in view of Mendelson-2006 to yield a pulse detector that can transmit data to an external device—i.e., handheld computing device—for monitoring” and “to enable a convenient and user-friendly interface with Aizawa's detector (which does not include a separate display/interface) and the ability to

⁹ At pages 47–48, the Petitioner refers to “Mendelson-2003” when discussing the receiver module and PDA. *See, e.g.*, Pet. 47 (contending that the modified system “includes Aizawa's wrist-worn sensor device that is in communication with Mendelson-2003's body-worn receiver module (below left) and PDA (below right)”). The cited disclosures, however, appear in Mendelson-2006, as Petitioner's citations confirm. *Id.* at 47–48 (citing Ex. 1016). Therefore, it appears these references to “Mendelson-2003” are inadvertent typographical errors, and that “Mendelson-2006” was intended. *See also id.* at 28–29 (referring to Mendelson-2006's receiver module and PDA).

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remotely monitor the user's physiological parameters." Pet. 28–29; *see, e.g.*, Ex. 1003 ¶¶ 85–86.

Patent Owner's Arguments

Patent Owner does not dispute Petitioner's contentions regarding the proposed combination with Mendelson-2006 to address this limitation. Patent Owner does argue, however, that "Mendelson 2006 confirms that Petitioner's arguments regarding Mendelson 2003's two-ring detector arrangement are meritless." PO Resp. 67. According to Patent Owner, Mendelson-2006 confirms that a skilled artisan would have used a single annular photodetector to reduce power consumption. *Id.* (citing Ex. 1016, 1, 4, Fig. 2).

Analysis

We are persuaded by Petitioner's undisputed contentions regarding this limitation. We agree that Mendelson-2006 teaches wireless communication between a sensor and a handheld computing device, i.e., a PDA. *See, e.g.*, Ex. 1016, 1–2 (describing system), Fig. 1 (sensor attached to skin), Fig. 3 (PDA). We are persuaded that Petitioner's stated reasoning for the proposed modification is sufficiently supported, including by the un rebutted testimony of Dr. Kenny, who opines that such a modification would enable a convenient and user-friendly interface with Aizawa's sensor. Ex. 1003 ¶ 86; *id.* ¶¶ 84–86, 109–111.

We also have considered Patent Owner's argument as it relates to limitations [c–e] and [g–i], but we do not agree. As noted above, Petitioner provides persuasive evidence demonstrating that the proposed combination would have realized power savings. *See, e.g.*, Ex. 1024, 3019, Table 1.

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- x. “[n] one or more processors configured to wirelessly receive one or more signals from the physiological sensor device, the one or more signals responsive to at least a physiological parameter of the user”

The cited evidence supports Petitioner’s undisputed contention that, in the proposed combination, Mendelson-2006’s receiver includes a microcontroller (processor) that wirelessly receives signals from Aizawa’s sensor and transmits them to the PDA. Pet. 50; *see, e.g.*, Ex. 1016, 1, 2 (“The information acquired by the Sensor Module is transmitted wirelessly via an RF link over a short range to a body-worn Receiver Module. The data processed by the Receiver Module can be transmitted wirelessly to a PDA.”), 3 (explaining that the PDA “has sufficient computational resources for the intended application” and “can also serve to temporarily store vital medical information received from the wearable unit”), Fig. 3 (displaying SpO₂ and HR data); Ex. 1003 ¶¶ 112–113.

- xi. “[o] a touch-screen display configured to provide a user interface, wherein: [p] the user interface is configured to display indicia responsive to measurements of the physiological parameter, and [q] an orientation of the user interface is configurable responsive to a user input”

The cited evidence supports Petitioner’s undisputed contention that, in the proposed combination, Mendelson-2006 describes a PDA with a touchscreen display configured to display indicia responsive to measurements of, e.g., SpO₂ and HR. Pet. 51–52; *see, e.g.*, Ex. 1016, 3 (“The use of a PDA . . . also provides a low-cost touch screen interface.”), Fig. 3 (displaying SpO₂ and HR data).

Petitioner acknowledges that “Mendelson-2006 does not explicitly state that an orientation of the GUI provided by the PDA is configurable responsive to a user input.” Pet. 52. However, Petitioner contends that a person of ordinary skill in the art would have understood that the “‘LabVIEW program’ . . . [and] the ‘Windows CE™’ operating system” would have “enabled users to dynamically switch the screen orientation between portrait and landscape modes.” *Id.* at 53; *see, e.g.*, Ex. 1003 ¶¶ 116–118.

Petitioner further contends that, in light of these teachings, a person of ordinary skill in the art “would have found it obvious to make an orientation of the PDA’s user interface configurable responsive to a user input, for the sake of user convenience.” Pet. 53; *see, e.g.*, Ex. 1003 ¶ 118. Petitioner’s stated reasoning for the proposed modification is sufficiently supported, including by the un rebutted testimony of Dr. Kenny, who testifies as to the convenience of the combination. *See, e.g.*, Ex. 1003 ¶¶ 114–118.

xii. “[r] a storage device configured to at least temporarily store at least the measurements of the physiological parameter.”

The cited evidence supports Petitioner’s undisputed contention that, in the proposed combination, Mendelson-2006 teaches that the PDA is configured to store vital medical information received from the wearable pulse oximeter, and that an ordinarily skilled artisan “would have understood that the vital medical information would have included measurements of the physiological parameters obtained by the physiological sensor device (e.g., HR).” Pet. 54; Ex. 1016, 3 (“The PDA can also serve to temporarily store vital medical information received from the wearable unit.”); Ex. 1003

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¶ 120. Thus, Petitioner contends that a person of ordinary skill in the art “would have configured a storage device of the PDA to at least temporarily store measurements of physiological parameters (e.g., HR).” Pet. 53; *see, e.g.*, Ex. 1003 ¶¶ 119–120.

xiii. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

6. Dependent Claims 2–18

Petitioner contends that claims 2–18 would have been obvious based on the same combination of prior art addressed above. These challenged claims all depend directly or indirectly from independent claim 1.

i. Dependent Claims 2–12, 14–16, 18

Petitioner identifies teachings in the prior art references that teach or suggest the limitations of these claims, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 54–70, 72–75. Petitioner also supports its contentions for these claims with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 121–146, 150–152, 154.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1. PO Resp. 68 (“[T]he Petition fails to establish that independent claims 1, 20, and 30 are obvious in view of the cited references of Ground 1 and therefore

fails to establish obviousness of any of the challenged dependent claims.”); *see supra* § II.D.5.

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that claims 2–12, 14–16, 18 would have been obvious over the combined teachings of the cited references and as supported by the testimony of Dr. Kenny.

ii. Dependent Claims 13 and 17

Dependent claim 13 ultimately depends from independent claim 1 and further recites “the protruding convex surface protrudes a height between 1 millimeter and 3 millimeters.” Ex. 1001, 46:49–51.

Dependent claim 17 ultimately depends from independent claim 1 and further recites “the protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters.” *Id.* at 47:1–3.

Petitioner contends that the sensor rendered obvious by the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006 would have included a cover with a protruding convex surface. *See supra* § II.D.5.viii. With respect to claim 13, Petitioner contends that a person of ordinary skill in the art “would have found it obvious that a device designed to fit on a user’s wrist would be on the order of millimeters,” consistent with Ohsaki’s disclosure that the device is in “intimate contact” with the user’s skin. Pet. 70–71 (citing, e.g., Ex. 1003 ¶¶ 148–149). Petitioner also contends that an ordinarily skilled artisan would have taken user comfort into account when establishing the dimensions of the device’s convex cover. *Id.* With these considerations in mind, Petitioner contends that, “in order to provide a comfortable cover that prevents slippage, the convex surface

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should protrude a height between 1 millimeter and 3 millimeters,” because “there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable to the user.” *Id.* (citing, e.g., Ex. 1003 ¶ 149). With respect to claim 17, Petitioner incorporates its contentions regarding claim 13. Pet. 75; Ex. 1003 ¶ 153.

Patent Owner argues that none of the cited references discloses the claimed height range and that Petitioner relies on hindsight reconstruction. PO Resp. 59 (citing, e.g., Ex. 2004 ¶¶ 121–125). Patent Owner also characterizes Dr. Kenny’s testimony as conclusory and unsupported. *Id.* at 71–72.

Petitioner is correct that, “[w]hen there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product . . . of ordinary skill and common sense.” *KSR*, 550 U.S. at 398. Petitioner has shown sufficiently that only a finite number of solutions existed with respect to the height of a convex protrusion on a tissue-facing sensor, which would have met the art-recognized goals of both (1) intimate contact between the sensor’s surface and the user and (2) user comfort. *See, e.g.*, Ex. 1014 ¶¶ 6, 25. Bearing in mind these considerations, we credit Dr. Kenny’s testimony that it would have been obvious, “in order to provide a comfortable cover featuring a protruding convex surface that prevents slippage, [that] the surface should protrude a height between 1 millimeter and 3 millimeters,” as recited in claim 13, and which further includes the claimed range of 2 to 3 millimeters as recited in claim 17. Ex. 1003 ¶ 149. Further, the record does

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not support that any new and unexpected results were achieved at the claimed height greater than 2 millimeters and less than 3 millimeters. *See, e.g.,* Ex. 1001, 23:43–50 (“The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.”).

We have considered Patent Owner’s argument, and Dr. Madisetti’s cited testimony. However, it is not dispositive that none of the cited references teaches the claimed range. PO Resp. 69; Ex. 2004 ¶ 121. Petitioner relies upon the knowledge, ability, and creativity of a person of ordinary skill in the art, not the teachings of a specific reference. Notably, Dr. Madisetti does not dispute Dr. Kenny’s position that there were a finite number of options available for the height of the convex surface. Ex. 2004 ¶¶ 121–125. Therefore, we do not agree that Petitioner’s contentions are rooted in impermissible hindsight. *See, e.g., In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) (“Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.”).

Accordingly, for the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that

claims 13 and 17 would have been obvious over the cited combination of references.

7. *Claims 20 and 22–30*

Independent claim 20 consists of limitations that are substantially similar to elements [a]–[j] and [l]–[m] of claim 1. *Compare* Ex. 1001, 45:2–49, *with id.* at 47:9–36. In asserting that claim 20 would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006, Petitioner refers to the contentions made regarding claim 1. *See* Pet. 75–76; Ex. 1003 ¶¶ 155–161.

Dependent claims 22–29 all depend directly or indirectly from independent claim 20. Petitioner identifies teachings in the prior art references that teach or suggest the limitations of these claims, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 76–79. Petitioner also supports its contentions for these claims with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 162–181.

Independent claim 30 includes limitations similar to limitations [a]–[r] of claim 1, and also includes additional recitations. *Id.* at 48:38–50:21 (reciting also a “substrate” and certain “preprocessing electronics”). In asserting that claim 30 would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Mendelson-2006, Petitioner refers to the contentions made regarding claim 1, as well as claims depending therefrom. *See* Pet. 79–82; Ex. 1003 ¶¶ 182–208.

Patent Owner does not present any argument for these claims other than those we have already considered with respect to independent claim 1 and dependent claims 13 and 18. PO Resp. 12–72.

For the same reasons discussed above, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 20 and 22–30 would have been obvious over the cited combination of references. *See supra* II.D.5–6; Ex. 1003 ¶¶ 155–208.

8. *Summary*

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 1–18, 20, and 22–30 would have been obvious over the cited combination of references.

E. Obviousness over the Combined Teachings of Aizawa, Mendelson-2003, Ohsaki, Mendelson-2006, and Beyer

Petitioner contends that claims 19 and 21 of the '194 patent would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, Mendelson-2006, and Beyer. Pet. 82–85.

1. Overview of Beyer (Ex. 1019)

Beyer is a U.S. patent titled “Cellular Phone/PDA Communication System,” and discloses a “cellular PDA communication system for allowing a plurality of cellular phone users to monitor each others’ location and status[and] to initiate cellular phone calls.” Ex. 1019, code (57). Beyer’s Figure 1 is reproduced below.



2. Analysis

Petitioner contends that claims 19 and 21 would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, Mendelson-2006, and Beyer. Pet. 82–85. Petitioner identifies teachings in the prior art references that teach or suggest the limitations of this claim, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 82–85; Ex. 1019, 1:6–15, Fig. 1. Petitioner also supports its contentions for this claim with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 209–212.

Patent Owner does not present any argument for these claims other than those we have already considered with respect to independent claim 1.

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PO Resp. 72 (“Ground 2 does not fix the deficiencies in Ground 1.”); *see supra* § II.D.

We have considered the evidence and arguments of record, including those directed to claim 1 and addressed above, and we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 19 and 21 would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, Mendelson-2006, and Beyer for the reasons discussed in the Petition and as supported by the testimony of Dr. Kenny. *See, e.g.*, Pet. 82–85; Ex. 1019, 1:6–15, Fig. 1; Ex. 1003 ¶¶ 209–212.

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III. CONCLUSION

In summary:¹⁰

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–18, 20, 22–30	103	Aizawa, Mendelson- 2003, Ohsaki, Mendelson- 2006	1–18, 20, 22– 30	
19, 21	103	Aizawa, Mendelson- 2003, Ohsaki, Mendelson- 2006, Beyer	19, 21	
Overall Outcome			1–30	

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1–30 of the '194 patent have been shown to be unpatentable; and

¹⁰ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,
Petitioner,

v.

MASIMO CORPORATION,
Patent Owner.

IPR2020-01733
Patent 10,702,195 B1

Before JOSIAH C. COCKS, ROBERT L. KINDER, and
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background

Apple Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–17 (“challenged claims”) of U.S. Patent No. 10,702,195 B1 (Ex. 1001, “the ’195 patent”). Paper 2 (“Pet.”). Masimo Corporation (“Patent Owner”) waived filing a preliminary response. Paper 6 (“PO Waiver”). We instituted an *inter partes* review of all challenged claims 1–17 on all grounds of unpatentability, pursuant to 35 U.S.C. § 314. Paper 7 (“Inst. Dec.”).

After institution, Patent Owner filed a Response (Paper 15, “PO Resp.”) to the Petition, Petitioner filed a Reply (Paper 19, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 22, “PO Sur-reply”). An oral hearing was held on February 9, 2022, and a transcript of the hearing is included in the record. Paper 32 (“Tr.”).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, Petitioner has met its burden of showing, by a preponderance of the evidence, that challenged claims 1–17 of the ’195 patent are unpatentable.

B. Related Matters

The parties identify the following matters related to the ’195 patent: *Masimo Corporation v. Apple Inc.*, Civil Action No. 8:20-cv-00048 (C.D. Cal.);

Apple Inc. v. Masimo Corporation, IPR2020-01520 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,258,265 B1);

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Apple Inc. v. Masimo Corporation, IPR2020-01521 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,292,628 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01523 (PTAB Sept. 9, 2020) (challenging claims of U.S. Patent No. 8,457,703 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01524 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,433,776 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01526 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 6,771,994 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01536 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01537 (PTAB Aug. 31, 2020) (challenging claims of U.S. Patent No. 10,588,553 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01538 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01539 (PTAB Sept. 2, 2020) (challenging claims of U.S. Patent No. 10,588,554 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01713 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,624,564 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01714 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01715 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,631,765 B1);

Apple Inc. v. Masimo Corporation, IPR2020-01716 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,702,194 B1);

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Apple Inc. v. Masimo Corporation, IPR2020-01722 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2);

Apple Inc. v. Masimo Corporation, IPR2020-01723 (PTAB Oct. 2, 2020) (challenging claims of U.S. Patent No. 10,470,695 B2); and

Apple Inc. v. Masimo Corporation, IPR2020-01737 (PTAB Sept. 30, 2020) (challenging claims of U.S. Patent No. 10,709,366 B1).

Pet. 95–96; Paper 3, 3–4.

Patent Owner further identifies the following pending patent applications, among other issued and abandoned applications, that claim priority to, or share a priority claim with, the '195 patent:

U.S. Patent Application No. 16/834,538;

U.S. Patent Application No. 16/449,143; and

U.S. Patent Application No. 16/805,605.

Paper 3, 1–2.

C. The '195 Patent

The '195 patent is titled “Multi-Stream Data Collection System for Noninvasive Measurement of Blood Constituents,” and issued on July 7, 2020, from U.S. Patent Application No. 16/834,467, filed March 30, 2020. Ex. 1001, codes (21), (22), (45), (54). The '195 patent claims priority through a series of continuation and continuation-in-part applications to Provisional Application Nos. 61/078,228 and 61/078,207, both filed July 3, 2008. *Id.* at codes (60), (63).

The '195 patent discloses a two-part data collection system including a noninvasive sensor that communicates with a patient monitor. *Id.* at 2:49–51. The sensor includes a sensor housing, an optical source, and several photodetectors, and is used to measure a blood constituent or analyte, e.g.,

oxygen or glucose. *Id.* at 2:40–46, 3:8–9. The patient monitor includes a display and a network interface for communicating with a handheld computing device. *Id.* at 2:56–59.

Figure 1 of the '195 patent is reproduced below.

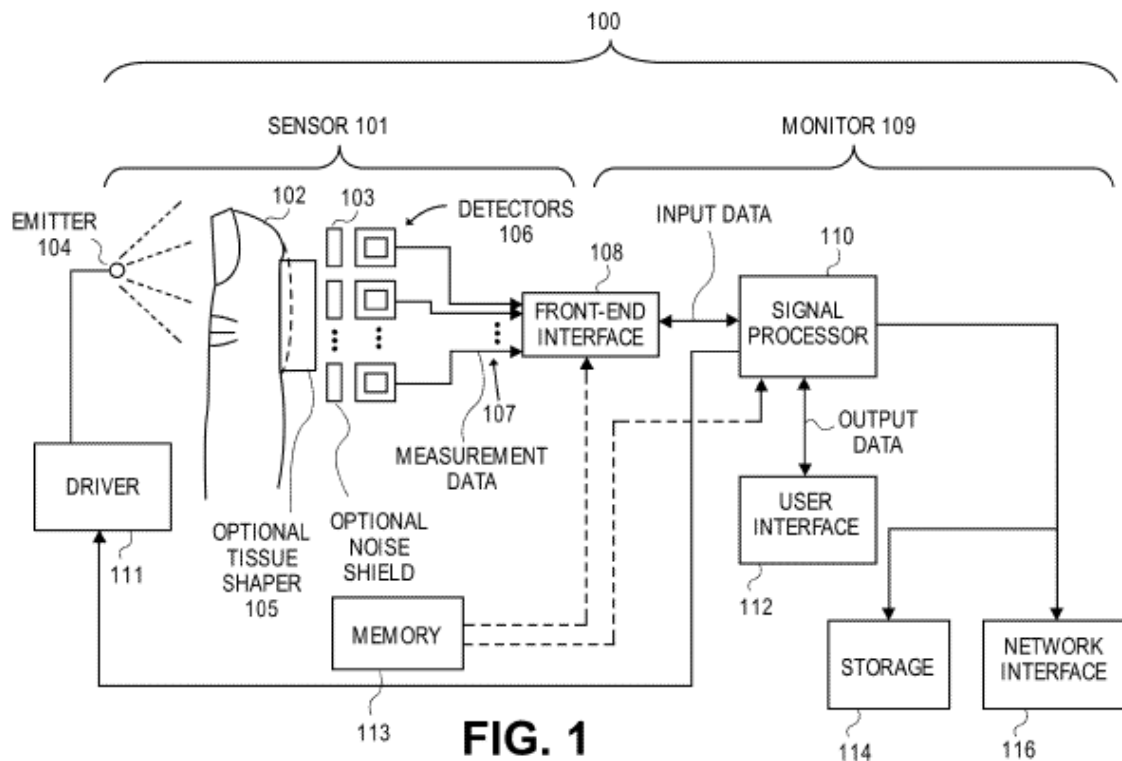


Figure 1 illustrates a block diagram of data collection system 100 including sensor 101 and monitor 109. *Id.* at 11:56–67. Sensor 101 includes optical emitter 104 and detectors 106. *Id.* at 12:1–5. Emitters 104 emit light that is attenuated or reflected by the patient’s tissue at measurement site 102. *Id.* at 14:11–16. Detectors 106 capture and measure the light attenuated or reflected from the tissue. *Id.* In response to the measured light, detectors 106 output detector signals 107 to monitor 109 through front-end interface 108. *Id.* at 14:16–19, 36–42. Sensor 101 also may include tissue shaper 105, which may be in the form of a convex surface that: (1) reduces

the thickness of the patient's measurement site; and (2) provides more surface area from which light can be detected. *Id.* at 11:7–23.

Monitor 109 includes signal processor 110 and user interface 112. *Id.* at 15:27–29. “[S]ignal processor 110 includes processing logic that determines measurements for desired analytes . . . based on the signals received from the detectors.” *Id.* at 15:32–35. User interface 112 presents the measurements to a user on a display, e.g., a touch-screen display. *Id.* at 15:57–67. The monitor may be connected to storage device 114 and network interface 116. *Id.* at 16:4–22.

The '195 patent describes various examples of sensor devices. Figures 14D and 14F, reproduced below, illustrate detector portions of sensor devices.

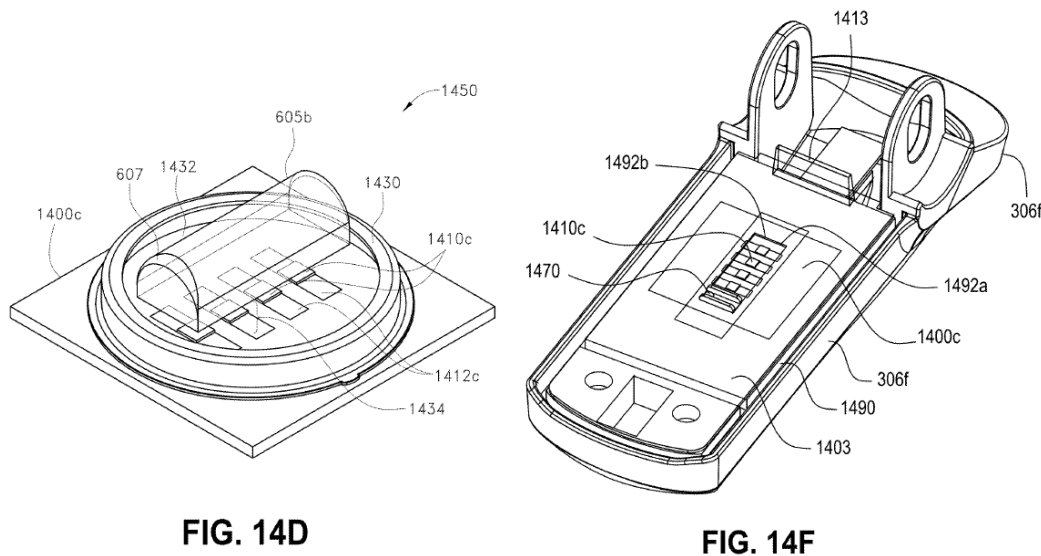
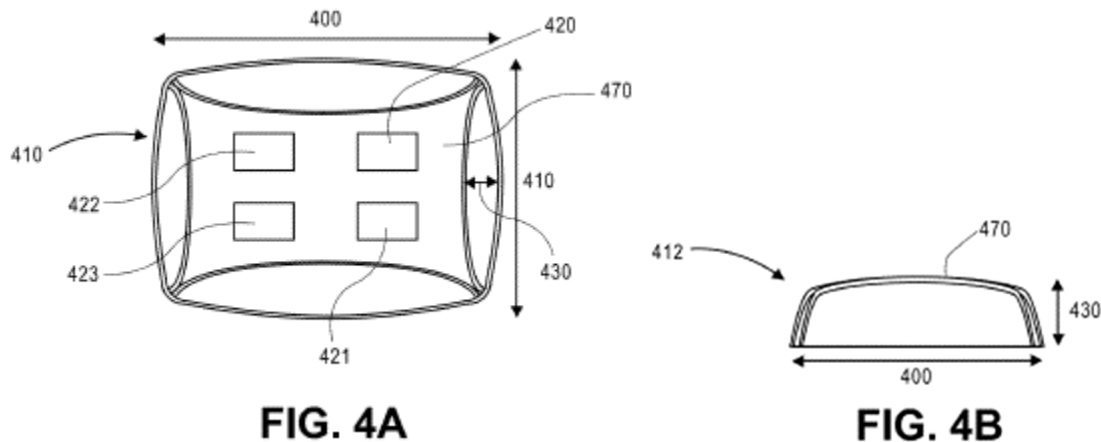


Figure 14D illustrates portions of a detector submount and Figure 14F illustrates portions of a detector shell. *Id.* at 6:54–57. As shown in Figure 14D, multiple detectors 1410c are located within housing 1430 and under transparent cover 1432, on which protrusion 605b (or partially cylindrical protrusion 605) is disposed. *Id.* at 35:51–54, 36:45–52.

Figure 14F illustrates a detector shell 306f including detectors 1410c on substrate 1400c. *Id.* at 37:25–33. Substrate 1400c is enclosed by shielding enclosure 1490 and noise shield 1403, which include window 1492a and window 1492b, respectively, placed above detectors 1410c. *Id.* Alternatively, cylindrical housing 1430 may be disposed under noise shield 1403 and may enclose detectors 1410c. *Id.* at 37:63–65.

Figures 4A and 4B, reproduced below, illustrate an alternative example of a tissue contact area of a sensor device.



Figures 4A and 4B illustrate arrangements of protrusion 405 including measurement contact area 470. *Id.* at 23:30–36. “[M]easurement site contact area 470 can include a surface that molds body tissue of a measurement site.” *Id.* “For example, . . . measurement site contact area 470 can be generally curved and/or convex with respect to the measurement site.” *Id.* at 23:53–55. The measurement site contact area may include windows 420–423 that “mimic or approximately mimic a configuration of, or even house, a plurality of detectors.” *Id.* at 23:61–24:8.

D. Illustrative Claim

Of the challenged claims, claims 1 and 16 are independent. Claim 1 is illustrative and is reproduced below.

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1. A user-worn physiological measurement device that defines a plurality of optical paths, the physiological measurement device comprising:

[a] one or more emitters configured to emit light into tissue of a user;

[b] a first set of photodiodes positioned on a first surface and surrounded by a wall that is operably connected to the first surface, wherein:

[c] the first set of photodiodes comprises at least four photodiodes, and

[d] the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream;

[e] a second set of photodiodes positioned on the first surface and surrounded by the wall, wherein:

[f] the second set of photodiodes comprises at least four photodiodes, and

[g] the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream; and

[h] a cover located above the wall and comprising a single protruding convex surface configured to be located between tissue of the user and the first and second sets of photodiodes when the physiological measurement device is worn by the user,

[i] wherein the physiological measurement device provides a plurality of optical paths, wherein each of the optical paths:

[j] exits an emitter of the one or more emitters,

[k] passes through tissue of the user,

[l] passes through the single protruding convex surface, and

[m] arrives at a corresponding photodiode of the at least one of the first or second sets of photodiodes, the

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corresponding photodiode configured to receive light emitted by the emitter after traversal by the light of a corresponding optical path of the plurality of optical paths and after attenuation of the light by tissue of the user.

Ex. 1001, 44:63–45:34 (bracketed identifiers [a]–[m] added). Independent claim 16 includes limitations substantially similar to limitations [a]–[h] and includes additional limitations drawn to “a plurality of windows,” “preprocessing electronics,” “one or more processors,” a “network interface,” a “touch-screen display,” and “storage device,” a “strap,” and “a plurality of optical paths.” *Id.* at 46:63–48:39.

E. Applied References

Petitioner relies upon the following references:

Ali et al., U.S. Patent No. 6,584,336 B1, filed March 1, 2000, issued June 24, 2003 (Ex. 1046, “Ali”);

Ohsaki et al., U.S. Patent Application Publication No. 2001/0056243 A1, filed May 11, 2001, published December 27, 2001 (Ex. 1014, “Ohsaki”);

Aizawa, U.S. Patent Application Publication No. 2002/0188210 A1, filed May 23, 2002, published December 12, 2002 (Ex. 1006, “Aizawa”);

Goldsmith et al., U.S. Patent Application Publication No. 2007/0093786 A1, filed July 31, 2006, published April 26, 2007 (Ex. 1027, “Goldsmith”); and

Y. Mendelson, et al., “Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter,” Proceedings of the 25th IEEE EMBS Annual International Conference, 3016–3019 (2003) (Ex. 1024, “Mendelson-2003”).

Pet. 1–2. Petitioner also submits, *inter alia*, the Declaration of Thomas W. Kenny, Ph.D. (Ex. 1003) and the Second Declaration of Thomas W. Kenny (Ex. 1060). Patent Owner submits, *inter alia*, the Declaration of Vijay K.

Madisetti, Ph.D. (Ex. 2004). The parties also provide deposition testimony from Dr. Kenny and Dr. Madisetti, including from this and other proceedings. *See* Exs. 1053–1054, 1056, 1059, 2006–2009, 2026–2027.

F. Asserted Grounds

Petitioner asserts that claims 1–17 are unpatentable based upon the following grounds (Pet. 1–2):

Claims Challenged	35 U.S.C. §	References/Basis
1–17	103	Aizawa, Mendelson-2003, Ohsaki, Goldsmith
1–17	103	Aizawa, Mendelson-2003, Ohsaki, Goldsmith, Ali

II. DISCUSSION

A. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b) (2019). Petitioner submits that no claim term requires express construction. Pet. 3. Patent Owner submits that claim terms should be given their ordinary and customary meaning, consistent with the Specification. PO Resp. 9.

We agree that no claim terms require express construction. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103 if “the differences between the subject matter sought to be patented and the prior art are such

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that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of non-obviousness.¹ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner identifies the appropriate level of skill in the art as that possessed by a person having “a Bachelor of Science degree in an academic

¹ Patent Owner does not present objective evidence of non-obviousness.

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discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information.” Pet. 3 (citing Ex. 1003 ¶¶ 21–22). “Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.” *Id.*

Patent Owner makes several observations regarding Petitioner’s identified level of skill in the art but, “[f]or this proceeding, [Patent Owner] nonetheless applies Petitioner’s asserted level of skill.” PO Resp. 9 (citing Ex. 2004 ¶¶ 30–32).

We adopt Petitioner’s assessment as set forth above, which appears consistent with the level of skill reflected in the Specification and prior art.

*D. Obviousness over the Combined Teachings of
Aizawa, Mendelson-2003, Ohsaki, and Goldsmith*

Petitioner contends that claims 1–17 of the ’195 patent would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Goldsmith. Pet. 6–85.

1. Overview of Aizawa (Ex. 1006)

Aizawa is a U.S. patent application publication titled “Pulse Wave Sensor and Pulse Rate Detector,” and discloses a pulse wave sensor that detects light output from a light emitting diode and reflected from a patient’s artery. Ex. 1006, codes (54), (57).

Figure 1(a) of Aizawa is reproduced below.

F I G . 1 (a)

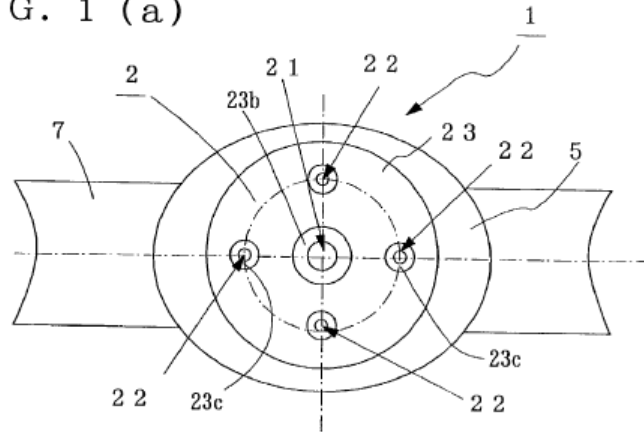


Figure 1(a) is a plan view of a pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(a), pulse wave sensor 2 includes light emitting diode (“LED”) 21, four photodetectors 22 symmetrically disposed around LED 21, and holder 23 for storing LED 21 and photodetectors 22. *Id.* Aizawa discloses that, “to further improve detection efficiency, . . . the number of the photodetectors 22 may be increased.” *Id.* ¶ 32, Fig. 4(a). “The same effect can be obtained when the number of photodetectors 22 is 1 and a plurality of light emitting diodes 21 are disposed around the photodetector 22.” *Id.* ¶ 33.

Figure 1(b) of Aizawa is reproduced below.

F I G . 1 (b)

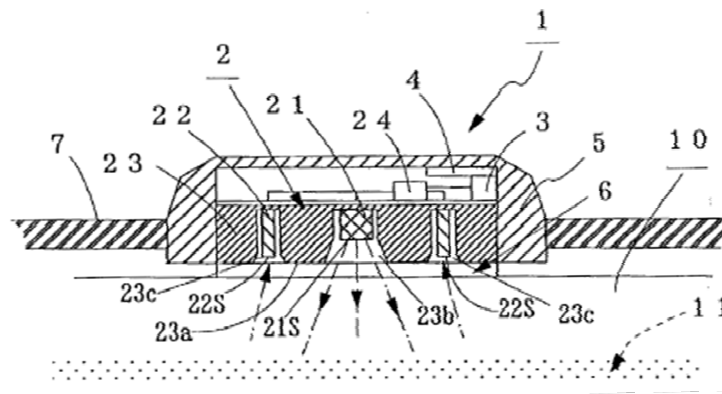


Figure 1(b) is a sectional view of the pulse wave sensor. *Id.* ¶ 23. As shown in Figure 1(b), pulse wave sensor 2 includes drive detection circuit 24 for detecting a pulse wave by amplifying the outputs of photodetectors 22. *Id.* ¶ 23. Arithmetic circuit 3 computes a pulse rate from the detected pulse wave and transmitter 4 transmits the pulse rate data to an “unshown display.” *Id.* The pulse rate detector further includes outer casing 5 for storing pulse wave sensor 2, acrylic transparent plate 6 mounted to detection face 23a of holder 23, and attachment belt 7. *Id.* ¶ 23.

Aizawa discloses that LED 21 and photodetectors 22 “are stored in cavities 23b and 23c formed in the detection face 23a” of the pulse wave sensor. *Id.* ¶ 24. Detection face 23a “is a contact side between the holder 23 and a wrist 10, respectively, at positions where the light emitting face 21s of the light emitting diode 21 and the light receiving faces 22s of the photodetectors 22 are set back from the above detection face 23a.” *Id.* ¶ 24. Aizawa discloses that “a subject carries the above pulse rate detector 1 on the inner side of his/her wrist 10 . . . in such a manner that the light emitting face 21s of the light emitting diode 21 faces down (on the wrist 10 side).” *Id.* ¶ 26. Furthermore, “the above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the artery 11 of the wrist 10. Thereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved.” *Id.* ¶¶ 26, 34.

2. Overview of Mendelson-2003 (Ex. 1024)

Mendelson-2003 is a journal article titled “Measurement Site and Photodetector Size Considerations in Optimizing Power Consumption of a Wearable Reflectance Pulse Oximeter,” which discusses a pulse oximeter sensor in which “battery longevity could be extended considerably by

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employing a wide annularly shaped photodetector ring configuration and performing SpO₂ measurements from the forehead region.” Ex. 1024, 3016.²

Mendelson-2003 explains that pulse oximetry uses sensors to monitor oxygen saturation (SpO₂), where the sensor typically includes light emitting diodes (LED) and a silicon photodetector (PD). *Id.* According to Mendelson-2003, when designing a pulse oximeter, it is important to offer “low power management without compromising signal quality.” *Id.* at 3017. “However, high brightness LEDs commonly used in pulse oximeters require[] relatively high current pulses, typically in the range between 100–200mA. Thus, minimizing the drive currents supplied to the LEDs would contribute considerably toward the overall power saving in the design of a more efficient pulse oximeter.” To achieve this goal, Mendelson-2003 discusses previous studies in which

the driving currents supplied to the LEDs . . . could be lowered significantly without compromising the quality of the [photoplethysmographic signal] by increasing the overall size of the PD Hence, by maximizing the light collected by the sensor, a very low power-consuming sensor could be developed, thereby extending the overall battery life of a pulse oximeter intended for telemedicine applications.

Id.

Mendelson-2003 discloses the prototype of such a sensor in Figure 1, which is reproduced below, and served as the basis for the studies evaluated in Mendelson-2003.

² Petitioner cites to the native page numbers appearing at the top of Exhibit 1024, rather than the added page numbering at the bottom of the pages. We follow Petitioner’s numbering scheme.

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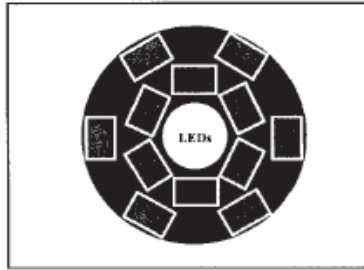


Figure 1 of Mendelson-2003 depicts a sensor configuration showing the relative positions of its PDs and LEDs. *Id.* As shown in Figure 1, “six PDs were positioned in a close inner-ring configuration at a radial distance of 6.0mm from the LEDs. The second set of six PDs spaced equally along an outer-ring, separated from the LEDs by a radius of 10.0mm.” *Id.* Mendelson-2003 also explains that “[e]ach cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter.” *Id.*

Mendelson-2003 reports the results of the studies as follows:

Despite the noticeable differences between the PPG signals measured from the wrist and forehead, the data plotted in Fig. 3 also revealed that considerable stronger PPGs could be obtained by widening the active area of the PD which helps to collect a bigger proportion of backscattered light intensity. The additional increase, however, depends on the area and relative position of the PD with respect to the LEDs. For example, utilizing the outer-ring configuration, the overall increase in the average amplitudes of the R and IR PPGs measured from the forehead region was 23% and 40%, respectively. Similarly, the same increase in PD area produced an increase in the PPG signals measured from the wrist, but with a proportional higher increase of 42% and 73%.

Id. at 3019.

Figure 2 illustrates a mechanism for detecting a pulse wave. *Id.* ¶ 13. Detecting element 2 includes package 5, light emitting element 6, light receiving element 7, and translucent board 8. *Id.* ¶ 17. Light emitting element 6 and light receiving element 7 are arranged on circuit board 9 inside package 5. *Id.* ¶¶ 17, 19.

“[T]ranslucent board 8 is a glass board which is transparent to light, and attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8.” *Id.* ¶ 17. “[T]he convex surface of the translucent board 8 is in intimate contact with the surface of the user’s skin,” preventing detecting element 2 from slipping off the detecting position of the user’s wrist. *Id.* ¶ 25. By preventing the detecting element from moving, the convex surface suppresses “variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user’s skin.” *Id.* Additionally, the convex surface prevents penetration by “noise such as disturbance light from the outside.” *Id.*

Sensor body 3 is connected to detecting element 2 by signal line 13. *Id.* ¶ 20. Signal line 13 connects detecting element 2 to drive circuit 11, microcomputer 12, and a monitor display (not shown). *Id.* Drive circuit 11 drives light emitting element 6 to emit light toward wrist 4. *Id.* Detecting element 2 receives reflected light which is used by microcomputer 12 to calculate pulse rate. *Id.* “The monitor display shows the calculated pulse rate.” *Id.*

4. *Goldsmith (Ex. 1027)*

Goldsmith is a U.S. patent application publication titled “Watch Controller for a Medical Device,” and discloses a watch controller device

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that communicates with an infusion device to “provid[e] convenient monitoring and control of the infusion pump device.” Ex. 1027, code (57).

Goldsmith’s Figure 9A is reproduced below.

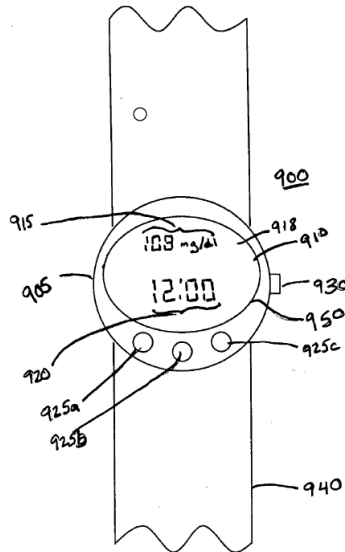


FIG. 9A

Figure 9A is a front view of a combined watch and controller device. *Id.* ¶ 30. As shown in Figure 9A, watch controller 900 includes housing 905, transparent member 950, display 910, rear-side cover 960, input devices 925a–c, 930, and wrist band 940. *Id.* ¶¶ 85–86, Fig. 9B.

Goldsmith discloses that the watch controller may interact with one or more devices, such as infusion pumps or analyte monitors. *Id.* ¶ 85; *see also id.* ¶ 88 (“The analyte sensing device 1060 may be adapted to receive data from a sensor, such as a transcutaneous sensor.”). Display 910 “may display at least a portion of whatever information and/or graph is being displayed on the infusion device display or on the analyte monitor display,” such as, e.g., levels of glucose. *Id.* ¶ 86. Additionally, the watch controller may communicate with a remote station, e.g., a computer, to allow data downloading. *Id.* ¶ 89 (including wireless).

5. Independent Claim 1

Petitioner presents undisputed contentions that claim 1 would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Goldsmith. Pet. 6–85.

i. “A user-worn physiological measurement device that defines a plurality of optical paths, the physiological measurement device comprising”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses a pulse sensor that defines a plurality of optical paths, and that Goldsmith teaches an analyte sensor that is part of a user-worn controller device that includes, e.g., a display.³ Pet. 36–37; *see, e.g.*, Ex. 1006 ¶¶ 2 (“a pulse wave sensor for detecting the pulse wave of a subject”), 27 (discussing optical paths), Fig. 1(b) (depicting two optical paths from emitter 21 to detectors 22 in Aizawa’s sensor); Ex. 1027 ¶¶ 85 (“a watch”), 88 (“analyte sensing device 1060”), Fig. 9A.

Petitioner further contends that a person of ordinary skill in the art would have found it obvious to incorporate Aizawa’s sensor “into Goldsmith’s integrated wrist-worn watch controller device that includes, among other features, a touch screen, network interface, and storage device” in order to receive and display data sensed by Aizawa’s sensor. Pet. 30–31; *see, e.g.*, Ex. 1003 ¶¶ 88–89. Petitioner contends this is consistent with Aizawa’s disclosure of a transmitter that transmits pulse rate data to a display. Pet. 29; Ex. 1003 ¶ 86. According to Petitioner, this would have

³ Whether the preamble is limiting need not be resolved because Petitioner shows sufficiently that the preamble’s subject matter is satisfied by the prior art.

“enable[d] a user to view and interact with heart rate data during exercise via the Goldsmith’s touch-screen display, and to enable heart rate data to be monitored by the user and/or others through any of the devices with which Goldsmith’s device can communicate.” Pet. 31; *see, e.g.*, Ex. 1003 ¶ 90. Petitioner asserts this would have been use of a known technique to improve similar devices in the same way. Pet. 32; *see, e.g.*, Ex. 1003 ¶ 91; *see also* Pet. 32–35 (also discussing physical incorporation); *see, e.g.*, Ex. 1003 ¶¶ 92–94 (same).

Patent Owner does not dispute this contention. *See* PO Resp. 65 (arguing only that Goldsmith does not remedy purported deficiencies, discussed *infra* at §§ II.D.5.iii–v). We are persuaded by Petitioner, wherein the proposed modification is supported by the unrebutted testimony of Dr. Kenny. *See, e.g.*, Ex. 1003 ¶¶ 86–96; Ex. 1006 ¶¶ 23 (“a transmitter for transmitting the above pulse rate data to an unshown display”), 35.

ii. “[a] one or more emitters configured to emit light into tissue of a user”

The cited evidence supports Petitioner’s undisputed contention that Aizawa discloses LED 21 that emits light into a user’s tissue. Pet. 37–38; *see, e.g.*, Ex. 1006 ¶ 23 (“LED 21 . . . for emitting light having a wavelength of a near infrared range”), 27 (explaining that light is emitted toward the wrist), Fig. 1(b) (depicting emitter 21 facing user tissue 10).

iii. “[b] a first set of photodiodes positioned on a first surface and surrounded by a wall that is operably connected to the first surface, wherein: [c] the first set of photodiodes comprises at least four photodiodes” and “[e] a second set of photodiodes positioned on the first surface and surrounded by the wall, wherein: [f] the

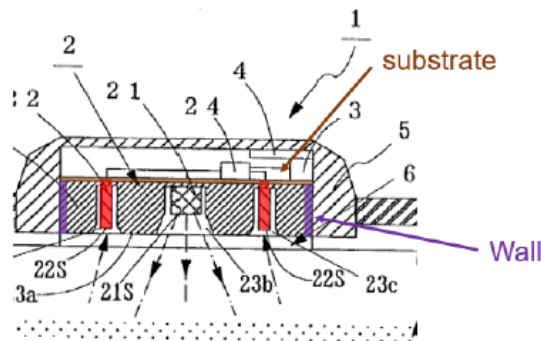
second set of photodiodes comprises at least four photodiodes”

Petitioner’s Undisputed Contentions

Petitioner contends that Aizawa discloses a first set of four photodiodes that are circularly arranged around a central emitter. Pet. 16–17 (citing, e.g., Ex. 1006 ¶ 23). Petitioner also contends that, in one embodiment, Aizawa discloses that eight or more detectors may be used to improve detection efficiency, but does not expressly teach a “second set of photodiodes,” as claimed. *Id.* at 17–18 (citing, e.g., Ex. 1006, Fig. 4(a)); *see also* Ex. 1003 ¶¶ 68–70.

Patent Owner does not dispute these contentions, and we agree with Petitioner. Aizawa discloses a set of “four phototransistors 22” that are disposed in a single ring around central emitter 21. Ex. 1006 ¶ 23, Figs. 1(a)–1(b). Aizawa also discloses that “the number of the photodetectors 22 may be increased” to further improve detection efficiency, and depicts in Figure 4(a) an embodiment where eight photodetectors 22 are disposed in a single ring around central emitter 21. *Id.* ¶ 32.

Petitioner also contends that Aizawa’s first set of photodiodes are positioned on the sensor’s first surface and surrounded by a wall that is operably connected to the surface, as shown below. Pet. 39.



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Petitioner's modified and annotated figure depicts Aizawa's sensor with Aizawa's first set of photodiodes 22 (in red shading) positioned on a first surface (identified as "substrate" with brown shading) and surrounded by a wall (identified as "wall" with purple shading). Patent Owner does not dispute these contentions, and we agree with Petitioner. Ex. 1006, Fig. 1(b).

Moreover, according to Petitioner, Mendelson-2003 teaches a sensor that uses two rings of photodiodes, which improve light collection efficiency, permit use of lower brightness LEDs, and reduce power consumption. Pet. 19; *see also* Ex. 1003 ¶ 71.

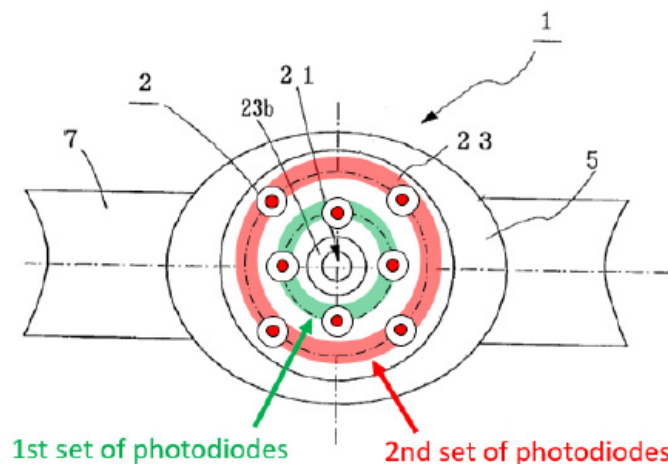
Patent Owner does not dispute these contentions regarding what Mendelson-2003 discloses, and we agree with Petitioner. Mendelson-2003 teaches an experimental sensor in which "six PDs [(photodetectors)] were positioned in a close inner-ring configuration . . . [and a] second set of six PDs [were] spaced equally along an outer-ring." Ex. 1024, 3017, Fig. 1 (depicting a prototype sensor with a near ring of photodetectors and a far ring of photodetectors). Based on experiments using the dual-ring sensor, as compared to sensors using only a near ring or only a far ring, Mendelson-2003 states that "considerabl[y] stronger PPGs [photoplethysmographic signals] could be obtained by widening the active area of the PD which helps to collect a bigger proportion of backscattered light intensity." *Id.* at 3019, Fig. 3. Mendelson-2003 also states that, "by combining both PD sets to simulate a single large PD area, it is possible to further reduce the driving currents of the LEDs without compromising the amplitude or quality of the detected PPGs." *Id.* at 3019, Fig. 4. Finally, Mendelson-2003 teaches that estimated battery life for the dual-ring sensor, as compared to sensors using only a near ring or only a far ring, "could be extended considerably." *Id.* at

3019, Table 1 (battery life of 52.5 days for the dual-ring sensor, compared to 45.8 and 20.3 days for the near ring or far ring sensors, respectively).

Petitioner’s Disputed Contentions

In view of these teachings, Petitioner contends that a person of ordinary skill in the art would have found it obvious to modify Aizawa to include an additional ring of detectors, as taught by Mendelson-2003, (i.e., a “second set”) to “advance[e] Aizawa’s goal of improving detection efficiency through increased power savings.” Pet. 18–19 (citing, e.g., Ex. 1003 ¶ 70), 38–41 (citing, e.g., Ex. 1003 ¶¶ 98–103), 46–48 (citing, e.g., Ex. 1003 ¶¶ 110–112). According to Petitioner, “by using Mendelson-2003’s power-saving (and thus efficiency-enhancing) PD configuration, the power consumption of a wrist-based pulse sensing device as in Aizawa can be reduced through use of a less bright and, hence, lower power-consuming LED.” *Id.* at 20–21 (citing, e.g., Ex. 1003 ¶ 73).

Petitioner provides “[a]n example implementation of adding an additional ring of detectors to Aizawa, as per Mendelson-2003,” which is reproduced below.



Pet. 21 (citing, e.g., Ex. 1003 ¶ 74). Petitioner’s modified and annotated figure depicts Aizawa’s sensor with Aizawa’s first set of photodiodes

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(depicted as connected by a green ring) and modified to include a second set of photodiodes as taught by Mendelson-2003 (depicted as connected by a red ring). Pet. 21, 41, 48. Petitioner contends this would have been the use of a known solution to improve similar systems in the same way, which “would have led to predictable results without significantly altering or hindering the functions performed by Aizawa’s sensor,” especially where Aizawa itself discloses adding extra detectors to improve light collection efficiency. *Id.* at 22 (citing, e.g., Ex. 1003 ¶ 76).

Petitioner also contends that, as modified, the second set of photodiodes would be positioned on the sensor’s first surface and surrounded by a wall that is operably connected to the surface. Pet. 47 (citing, e.g., Ex. 1003 ¶ 111).

Patent Owner’s Arguments

Patent Owner’s arguments address limitations [b]–[g] together. *See* PO Resp. 54–64. As such, Patent Owner’s arguments, the parties’ Reply and Sur-reply briefing, and our analyses, are presented below in connection with limitations [d] and [g]. *See infra* § II.D.5.iv.

- iv. “[d] the photodiodes of the first set of photodiodes are connected to one another in parallel to provide a first signal stream”
and
“[g] the photodiodes of the second set of photodiodes are connected to one another in parallel to provide a second signal stream”*

Petitioner’s Undisputed Contentions

Petitioner contends that a signal stream is sent from Aizawa’s set of photodetectors 23 to drive detection circuit 24, which amplifies the outputs of the photodetectors. Pet. 17 (citing, e.g., Ex. 1006 ¶ 23; Ex. 1003 ¶ 68).

Patent Owner does not dispute this contention, and we agree with Petitioner. Aizawa discloses that “drive detection circuit 24 [is] for detecting a pulse wave by amplifying the outputs of the photodetectors 22.” Ex. 1006 ¶ 23.

Petitioner additionally contends that Mendelson-2003 teaches that each set of photodiodes, i.e., its near ring and far ring, are wired in parallel, thereby providing a distinct signal stream for each ring. Pet. 19, 42–43, 48 (citing, e.g., Ex. 1024, 3017).

Patent Owner does not dispute this contention regarding what Mendelson-2003 discloses, and we agree with Petitioner. Mendelson-2003 teaches that “[e]ach cluster of six PDs were wired in parallel and connected through a central hub to the common summing input of a current-to-voltage converter.” Ex. 1024, 3017.

Petitioner’s Disputed Contentions

In view of these teachings, Petitioner contends that a person of ordinary skill in the art “would have recognized and/or found it obvious that the first set of photodiodes [in the modified system of Aizawa and Mendelson-2003, *see supra* § II.D.5.iv] are connected to one another in parallel to provide a first signal stream in the manner claimed,” and “the second set of photodiodes . . . are connected to one another in parallel to provide a second signal stream,” as taught by Mendelson-2003. Pet. 40–41 (citing, e.g., Ex. 1003 ¶¶ 104–109), 48 (citing, e.g., Ex. 1003 ¶ 113). Petitioner contends this “would have led to predictable results without significantly altering or hindering the functions performed by Aizawa’s sensor.” *Id.* at 22 (citing, e.g., Ex. 1003 ¶ 76).

According to Petitioner, this arrangement would have provided known benefits. Pet. 43–46. For example, Petitioner contends that a person of ordinary skill in the art “would have known that connecting multiple photodiodes together in parallel allows the current generated by the multiple photodiodes in [each] set/ring to be added to one another, thereby resulting in a larger total current akin to what would be generated from a single, large detector.” *Id.* at 42. According to Petitioner, this was “a routine and conventional design choice.” *Id.* at 43. Further, “monitoring each signal stream (from each ring of detectors) separately allows the system to determine when the sensor device is so severely located that its position should be adjusted,” and can help detect motion artifacts. *Id.* at 43–44 (citing Ex. 1003 ¶ 107).

Petitioner also argues that a person of skill in the art would have known that “the photodiodes in the far ring (i.e., second set of photodiodes) would receive reflected light having a lower intensity than that received by the photodiodes in the near ring (i.e., first set of photodiodes) and would have been motivated and found it obvious to account for this discrepancy,” e.g., by “keep[ing] each ring separately wired and connected to its own amplifier . . . to thereby keep the magnitude of the current signals provided by each ring approximately the same before being combined and transmitted to the arithmetic circuit 3.” *Id.* at 44–46 (citing Ex. 1003 ¶¶ 108–109); *id.* at 48 (citing Ex. 1003 ¶ 113).

Patent Owner’s Arguments

Patent Owner disputes Petitioner’s contentions that it would have been obvious (1) to modify Aizawa to include a second set of at least four photodiodes, and (2) to wire the photodiodes of the first set in parallel to

provide a first signal stream and to wire the photodiodes of the second set in parallel to provide a second signal stream. PO Resp. 54–64; PO Sur-reply 23–29.

First, Patent Owner argues this proposed modification changes Aizawa’s principle of operation. Specifically, Patent Owner claims that “Aizawa’s approach monitors different individual detector signals and calculates pulse rate based on each individual photodetector signal” and, in contrast to the proposed modification, “does not measure aggregated signals from detectors connected in parallel.” PO Resp. 55 (citing Ex. 1006 ¶¶ 7, 19, 23, 27–29, 32, 36; Ex. 2004 ¶ 102; Ex. 2026, 76:13–22, 79:22–80:3). According to Patent Owner, the proposed modification “eliminates Aizawa’s *core feature*—the ability to monitor pulse using the output of each *individual* detector, which Aizawa indicates avoids displacement problems.” *Id.* at 56–57 (citing, e.g., Ex. 2004 ¶¶ 104–105).

Second, Patent Owner argues this proposed modification would have resulted in increased power consumption. *Id.* at 57. According to Patent Owner, Mendelson-2003 states that its power savings is caused by “increasing the *number of detectors* and thus the detector area, not the two-ring structure.” *Id.* at 58 (citing Ex. 1024, 2; Ex. 2004 ¶ 106). Moreover, Patent Owner argues that Aizawa already discloses a way to improve detection efficiency—by including eight detectors in a single ring. *Id.* at 58 (citing Ex. 1006 ¶ 32, Fig. 4A; Ex. 2004 ¶ 107). In light of this teaching, Patent Owner argues that adding a second ring is unfounded and unnecessary, especially where the second ring of detectors “would receive substantially lower light intensity requiring greater power consumption to utilize than additional detectors added to the ‘inner’ ring.” *Id.* at 58–60

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(citing, e.g., Ex. 2004 ¶¶ 108–109; Ex. 2026, 55:7–17, 56:6–16, 59:14–60:7, 100:6–101:6, 102:5–17, 112:3–16). “Petitioner never explains why, given these straightforward options to increase signal strength, a [person of ordinary skill in the art] would instead add an entire new circle of detectors farther from the emitter.” *Id.* at 60.

Third, Patent Owner argues that Mendelson-2003 provides only an experimental detector configuration, which would fail to provide the alleged benefits. Specifically, Patent Owner argues that Mendelson-2003 “uses its particular configuration for specific experiments comparing light intensity and LED drive currents for detectors arranged different distances from central emitters,” and “teaches no benefits for this arrangement in practice.” *Id.* at 60–62 (citing Ex. 1024, 4; Ex. 2004 ¶¶ 111–112). To the contrary, Patent Owner alleges that Mendelson-2003 actually prefers a single detector ring that outputs a single signal stream: “Mendelson 2003 explains it ‘combin[ed] both PD sets to simulate **a single** large PD area,’ and notes ‘battery longevity could be extended considerably by employing **a** wide annular PD,’ which has a single signal stream—not two different signal streams from two different parallel-connected rings.” *Id.* at 61 (citing, e.g., Ex. 2026, 87:8–88:1, 91:15–92:7).⁴ Thus, according to Patent Owner, even

⁴ Patent Owner also criticizes the Petition’s discussion of Exhibit 1025 (U.S. Patent No. 6,801,799 (“Mendelson ’799”). Mendelson ’799, which is not included in Petitioner’s identification of the asserted ground of unpatentability. PO Resp. 62–63; PO Sur-reply 28–29. We discern no error in Petitioner’s identification of Mendelson ’799. The nature of Petitioner’s reliance on Mendelson ’799 in support of this ground is explained clearly in the Petition, even if Mendelson ’799 is not listed as an additional reference in the identification of the ground. Thus, the Petition complies with 35 U.S.C. § 312(a)(3) (stating an IPR petition must “identif[y], in writing and

if a skilled artisan would have added a second ring of detectors to Aizawa, they “would not have kept the first and second ring of detectors separate or separately amplified the aggregated signals”; instead, they would have “combin[ed] both PD sets to simulate a single large PD area,” where “battery longevity could be extended considerably by employing a wide annular PD.” *Id.* at 64 (quoting Ex. 1024, 4; citing Ex. 2004 ¶ 116).

Finally, Patent Owner argues that the proposed combination “introduces signal processing problems requiring a further redesign for Aizawa’s sensor” to include a second amplifier to account for signals of different strengths between the near and far rings. *Id.* at 63–64 (citing Ex. 2004 ¶ 115). Patent Owner alleges this demonstrates that a skilled artisan would not have added a second ring of detectors, as proposed, but instead would have increased the number of detectors in Aizawa’s single ring. *Id.* at 64.

Petitioner’s Reply

Petitioner replies that Patent Owner mischaracterizes Aizawa’s principle of operation. Pet. Reply 32–34. Specifically, Petitioner contends that Aizawa’s detector ring is connected in parallel, or at least that a person of ordinary skill in the art would have recognized that parallel connection would have been a known implementation detail, which allows a signal to be detected even if one of the multiple sensors is displaced on the user. *Id.* at 33 (citing Ex. 1003 ¶¶ 105–106; Ex. 1060 ¶ 62; Ex. 2026, 72:3–9). Moreover, Petitioner argues that Aizawa lacks any disclosure of individually monitoring signals from each photodetector. *Id.* at 34.

with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge . . .”).

Petitioner reiterates its position that adding a second ring would collect a bigger portion of backscattered light, and would motivate the proposed combination. *Id.* at 34–35 (citing, e.g., Ex. 1060 ¶¶ 64–66). Petitioner also disputes that such a modification would increase power, noting that it is the emitters, not the detectors, that consume most power in the system. *Id.* at 35–36 (citing, e.g., Ex. 1060 ¶ 67). Moreover, Petitioner contends that by widening the detection area with a second ring, the system would capture additional light which would allow a lower brightness, and lower power, emitter to be used. *Id.*

Petitioner disputes Patent Owner’s characterization of Mendelson-2003’s as purely experimental, and alleges that Mendelson-2003 makes clear that employing two rings outputting two signal streams is equivalent to employing a wider single ring of detectors, and provides associated benefits. *Id.* at 36–38 (citing, e.g., Ex. 1060 ¶ 70).

Patent Owner’s Sur-reply

Patent Owner reiterates its position that Aizawa concerns individual monitoring, which Patent Owner alleges is a “key feature of Aizawa’s sensor,” in order to avoid problems associated with sensor displacement. PO Sur-reply 23–24. Patent Owner also reiterates its positions that the proposed modified sensor would consume more power, and that Aizawa’s disclosed embodiment with eight detectors in a single ring would have been preferred. *Id.* at 25.

Analysis

We have considered the parties’ arguments and cited evidence, and we are persuaded by Petitioner’s contentions. As discussed above, Aizawa discloses a sensor with a first set of four phototransistors 22 as claimed,

which are disposed in a single ring around central emitter 21. Ex. 1006 ¶ 23, Figs. 1(a)–1(b). Mendelson-2003 teaches a sensor with a dual-ring configuration, where a first inner ring includes six photodetectors, and a second outer ring includes an additional six photodetectors. Ex. 1024, 3017, Fig. 1. Mendelson-2003 also states that by using this dual-ring configuration to simulate a wide photodetector area, stronger signals could be obtained, drive currents could be reduced, and battery life could be extended. *Id.* at 3019, Fig. 3, Fig. 4.

In light of these explicit teachings, we are persuaded by Petitioner’s contention that a person of ordinary skill in the art would have found it obvious to include a second set of detectors in Aizawa’s sensor, as taught by Mendelson-2003, to realize the benefits taught by Mendelson-2003, i.e., stronger signals with reduced power consumption. Pet. 18–22. We credit Dr. Kenny’s testimony that this would have been the use of a known solution—a sensor with dual detector rings as taught by Mendelson-2003—to improve similar systems—Aizawa’s sensor with one detector ring—in the same way, which “would have led to predictable results without significantly altering or hindering the functions performed by Aizawa’s sensor,” especially where Aizawa itself discloses adding extra detectors to improve light collection efficiency. Ex. 1003 ¶ 76.

We also credit Dr. Kenny’s testimony that, as taught by Mendelson-2003, it would have been obvious to connect the photodetectors of each set in parallel to provide first and second signal streams, respectively, and that this would have led to predictable results. Ex. 1003 ¶ 76 (predictable), 93, 104–106 (first set), 113 (second set). Indeed, the two rings taught by Mendelson-2003 are disclosed as being “wired in parallel and connected

through a central hub to the common summing input of a current-to-voltage converter.” Ex. 1024, 3017. Dr. Kenny explains numerous advantages associated the parallel connections taught by Mendelson-2003, such as monitoring for displacement, accounting for motion artifacts, and compensating for the relative decrease in light that reaches the outer ring, which cannot be achieved with a single signal stream. Ex. 1003 ¶¶ 107–109.

We are also persuaded by Petitioner that, as modified, the second set of photodiodes would be positioned on the sensor’s first surface and surrounded by a wall that is operably connected to the surface, in the same manner as the first set are arranged. Pet. 37, 47; Ex. 1003 ¶¶ 99–102, 110–111.

We have considered Patent Owner’s arguments but find them to be misplaced. First, we do not agree that Aizawa discloses the ability to individually monitor individual detectors as a “key feature” (PO Resp. 54; PO Sur-reply 24) of its sensor. We discern no persuasive support for this position in Aizawa. Aizawa does not discuss individual monitoring at all, at least not clearly, and does not discuss individual monitoring as a solution to sensor displacement. Rather, Aizawa explains that its sensor includes four photodetectors 22 and that “reflected light is detected by the plurality of photodetectors 22.” Ex. 1006 ¶¶ 23, 27. Aizawa also explains that its sensor includes a “drive detection circuit for detecting a pulse wave by amplifying the outputs of the photodetectors 22.” *Id.* ¶ 23. These disclosures indicate that Aizawa does not monitor each photodetector 22 individually to ascertain the pulse wave but, rather, utilizes “the outputs” of *all* of the photodetectors together.

This understanding is consistent with Aizawa's disclosure of sensor displacement. As Patent Owner correctly notes, Aizawa recognizes a problem with sensor displacement, in which "no output signal can be obtained" if the sensor's detectors are placed away from an artery. *Id.* ¶ 7. Aizawa solves this problem by avoiding a "linear[]" detector arrangement, such that "[e]ven when the attachment position of the sensor is dislocated, a pulse wave can be detected accurately." *Id.* ¶ 9. Indeed, Aizawa is clear that, in its preferred embodiment, it is the disposition of photodetectors 22 in "a circle concentric to the light emitting diode 21" that enables accurate pulse detection even when the sensor is dislocated. *Id.* ¶ 27. Aizawa does not discuss individual monitoring in relation to sensor dislocation.

We have examined Patent Owner's alleged support for the importance of individual monitoring and find it unavailing. *See, e.g.*, PO Resp. 55–56 (citing Ex. 1006 ¶¶ 7, 19, 23, 27–29, 32, 36; Ex. 2004 ¶ 102; Ex. 2026, 76:13–22, 79:22–80:3). Patent Owner identifies Figure 3, which depicts a "diagram of a pulse wave which is the output of a photodetector." Ex. 1006 ¶¶ 19 (emphasis added), 28 ("the above photodetector 22"). Patent Owner seems to place importance on the use of the article "a" or "the" photodetector, in the singular. PO Resp. 88; PO Sur-reply 23. However, we discern no significance in the singular use. In discussing this Figure, Aizawa does not discuss monitoring an individual photodetector, or describe that as a "key feature"; instead, Aizawa explains that drive detection circuit 24 amplifies the detected pulse wave and transmits it to arithmetic circuit 3, which compares it to a threshold value to calculate a pulse rate. Ex. 1006 ¶ 28. We discern that this discussion of how the circuits process a signal from "a" (or "the") photodetector is merely exemplary of the process; Patent

Owner has not pointed to any persuasive support for its position that this somehow indicates a “key feature” of Aizawa is individual monitoring. As noted above, Aizawa plainly discloses that it is the signals from *the plurality* of photodetectors that is used to determine a pulse wave. *Id.* ¶¶ 23, 27. Nothing in Figure 3 or paragraph 28 clearly contradicts that disclosure.

We have considered the cited testimony of Dr. Madisetti, which Patent Owner relies upon as support for its position, but we find it unavailing as well. Dr. Madisetti’s testimony includes the same citations presented by Patent Owner, none of which demonstrates individual monitoring. Ex. 2004 ¶ 102. Thus, we determine this testimony to be conclusory and entitled to little weight.

We do recognize, as did Dr. Kenny during his deposition, that Aizawa does not provide extensive discussion of the algorithms through which Aizawa determines a pulse wave. *See, e.g.*, Ex. 2026, 80:8–18 (“It doesn’t describe the algorithm in detail. It just says amplifies the signals from the detectors and then performs whatever function takes place inside the arithmetic circuit which I think computes the number of times the signal crosses the threshold value to calculate the pulse rate, but there’s not a clearly described precise algorithm for what goes on. It’s left for one of ordinary skill in the art to process the waveforms and, and count the crossings of the threshold and determine the pulse rate.”). Nonetheless, we decline Patent Owner’s invitation to import into Aizawa’s disclosure a “key feature” of individual monitoring that is not identified by Aizawa with any reasonable clarity. Again, as noted above, Dr. Madisetti provides no further support for the conclusory position advanced by Patent Owner.

By contrast, we credit Dr. Kenny’s testimony, which is consistent with Aizawa’s express disclosure of detecting a pulse wave from “the plurality of photodetectors” (Ex. 1006 ¶ 27), that:

connecting multiple photodetectors together in parallel allows the current generated by the multiple photodetectors to be added to one another, which would subsequently ensure that even if one of multiple sensors connected in parallel were to be displaced so as to receive no signal, the fact that all the sensors are connected in parallel such that their signals are summed means that a signal will still be detected, in accordance with Aizawa’s objective.

Ex. 1060 ¶ 62. Moreover, we agree with Dr. Kenny that “there is no disclosure anywhere in Aizawa to suggest that it is even capable of somehow monitoring the signals of each photodetector, and there is certainly no need to do so if its sensors are connected in parallel.” *Id.* Thus, considering the express disclosure of Aizawa and the competing testimony of the parties’ experts, we credit that of Dr. Kenny.

Patent Owner’s second argument—that the proposed modification would have resulted in increased power consumption—is plainly contradicted by Mendelson-2003’s disclosure. Table 1 of Mendelson-2003 is reproduced below.

Table 1. Comparison of estimated battery life for different PD configurations. Values based on forehead measurements for a typical 220mAh coin size battery.

PD CONFIGURATION	BATTERY LIFE [Days]
Near	45.8
Far	20.3
Near+Far	52.5

Table 1 includes three rows, each associating a different photodetector configuration with an estimated battery life. Ex. 1024, 3019. The table indicates that a configuration consisting of only a near ring of photodetectors

results in 45.8 days of battery life; a configuration consisting of only a far ring of photodetectors results in 20.3 days of battery life; and a configuration consisting of both a near ring and a far ring of photodetectors results in 52.5 days of battery life. *Id.* In describing this table, Mendelson-2003 states, “the considerable differences in the estimated power consumptions clearly points out the practical advantage gained by using a reflection sensor comprising a large ring-shaped PD area to perform SpO₂ measurements,” which in this case, was realized by the combination of a near and far ring of detectors, akin to the modification proposed by Petitioner. *Id.* Thus, we do not agree with Patent Owner’s argument that power consumption would increase if a second ring of detectors were added to Aizawa’s sensor; Mendelson-2003 plainly suggests the opposite and supports Petitioner’s contention that the proposed modification would result in a power savings over a single ring.

We also do not agree with the argument that a person of ordinary skill in the art would not make the proposed modification because Aizawa already discloses a way to improve detection efficiency, e.g., by including more detectors in a single ring. PO Resp. 58 (citing Ex. 1006 ¶ 32, Fig. 4A; Ex. 2004 ¶ 107). Aizawa explains that the photodetector arrangement of its single-ring preferred embodiment “is not limited” and suggests, “[f]or example,” that “the number of photodetectors 22 may be increased.” Ex. 1006 ¶ 32. Aizawa does not limit the increase in photodetectors to being included in only the existing single ring of detectors, i.e., the first set. Nothing in this disclosure teaches against adding a second set, as proposed by Petitioner for the well-supported reasons identified in Mendelson-2003 and further discussed by Dr. Kenny.

Patent Owner's third argument—that Mendelson-2003 is experimental and would not provide the alleged benefits—likewise fails. Patent Owner's suggestion that Mendelson-2003 teaches using a single large, wide detector ring that outputs a single signal stream is unfounded. The analysis provided in Mendelson-2003 explicitly compares a dual-ring arrangement to both a single near ring and a single far ring. *See, e.g.*, Ex. 1024, Fig. 3, Fig. 4, Table 1 (all comparing near, far, and near + far arrangements). Mendelson-2003 explains that the dual-ring arrangement “simulate[s] a single large PD area” and realizes benefits in LED power requirements. *Id.* at 3019. That Mendelson-2003 *simulates* a single ring by using two discrete rings demonstrates the fallacy of Patent Owner's argument.

Finally, we disagree with Patent Owner's argument that a person of ordinary skill in the art would not have made the proposed combination because it “introduces signal processing problems requiring a further redesign for Aizawa's sensor” to include a second amplifier to account for signals of different strengths between the near and far rings. PO Resp. 63–64. A person of ordinary skill in the art must be presumed to understand something about the art beyond what is disclosed in the references. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962). After all, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). Neither Patent Owner nor Dr. Madisetti assert that adding a second amplifier would be beyond the level of skill in the art or would introduce any specific problems, beyond its mere addition. We credit Dr. Kenny's testimony that a person of ordinary skill would have recognized that, in order to account for the disparate currents generated by the two rings, the rings would be separately wired with

separate amplifiers (Ex. 1003 ¶ 109) and that this would have been a routine and conventional design choice, within the level of ordinary skill in the art (*id.* ¶ 106).

For the foregoing reasons, we are persuaded by Petitioner's contentions.

v. “[h] a cover located above the wall and comprising a single protruding convex surface configured to be located between tissue of the user and the first and second sets of photodiodes when the physiological measurement device is worn by the user”

Petitioner's Undisputed Contentions

Petitioner contends that Aizawa “teaches a light permeable cover in the form of an acrylic transparent plate 6 . . . that is mounted at the detection face 23a” of the sensor, i.e., between the user's tissue and Aizawa's photodetectors, to provide “improved adhesion between the detector and the wrist to ‘further improv[e] the detection efficiency of a pulse wave.’”

Pet. 8–9 (citing Ex. 1006 ¶ 30, Fig. 1(b); Ex. 1003 ¶¶ 53–54). Patent Owner does not dispute this contention, and we agree with Petitioner. Aizawa discloses that “acrylic transparent plate 6 is provided on the detection face 23a of the holder 23 to improve adhesion to the wrist 10.” Ex. 1006 ¶ 34, Fig. 1(b) (depicting transparent plate 6 between sensor 2 and wrist 10).

Petitioner also contends that Ohsaki teaches a wrist-worn sensor that includes a “translucent board” having a single protruding convex surface that contacts the user's skin. Pet. 12, 49. Patent Owner does not dispute this contention, and we agree with Petitioner. Ohsaki discloses that sensor 1 includes detecting element 2 and sensor body 3, and is “worn on the back side of the user's wrist.” Ex. 1014 ¶ 16. Ohsaki discloses that detecting

element 2 includes package 5 and “translucent board 8[,which] is a glass board which is transparent to light, [and is] attached to the opening of the package 5. A convex surface is formed on the top of the translucent board 8.” *Id.* ¶ 17. As seen in Ohsaki’s Figure 2, translucent board 8 has a protruding convex surface, and is located between the user’s tissue and Ohsaki’s detecting element. *Id.* ¶ 17 (“The translucent board 8 is . . . attached to the opening of the package 5.”), Fig. 2.

Petitioner’s Disputed Contentions

Petitioner further contends that a person of ordinary skill in the art would have found it obvious “to modify the sensor’s flat cover [in Aizawa] . . . to include a lens/protrusion . . . similar to Ohsaki’s translucent board 8, so as to [1] improve adhesion between the user’s wrist and the sensor’s surface, [2] improve detection efficiency, and [3] protect the elements within sensor housing.” Pet. 25 (citing, e.g., Ex. 1003 ¶ 80; Ex. 1014 ¶ 25), 49 (citing, e.g., Ex. 1003 ¶ 114). Petitioner contends that Ohsaki’s convex surface is in “intimate contact” with the user’s tissue, which prevents slippage of the sensor and increases signal strength because “variation of the amount of the reflected light . . . that reaches the light receiving element 7 is suppressed” and because “disturbance light from the outside” is prevented from penetrating board 8, as compared to a sensor with a flat surface. *Id.* at 23–24 (citing, e.g., Ex. 1003 ¶¶ 78–79; quoting Ex. 1014 ¶¶ 15, 17, 25).

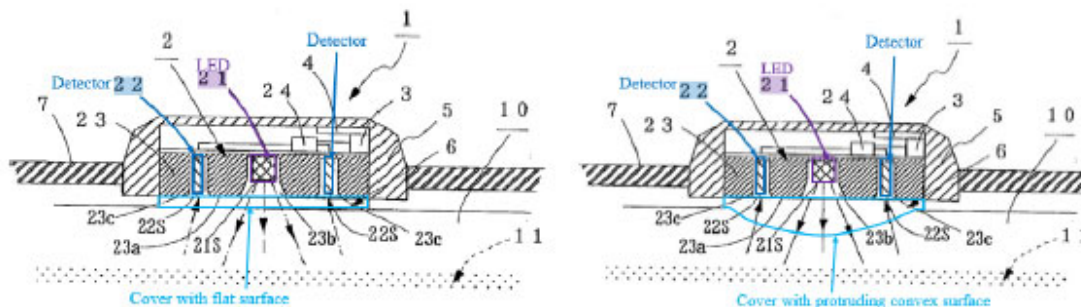
Petitioner contends this modification would have been “nothing more than the use of a known technique to improve similar devices in the same way,” i.e., “simply improving Aizawa-Mendelson-2003’s transparent plate 6 that has a flat surface to improve adhesion to a subject’s skin and reduce variation in the signals detected by the sensor.” Pet. 26 (citing Ex. 1003

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¶ 81). Further according to Petitioner, “the elements of the combined system would each perform functions they had been known to perform prior to the combination—Aizawa-Mendelson-2003’s transparent plate 6 would remain in the same position, performing the same function, but with a convex surface as taught by Ohsaki.” *Id.*

To illustrate its proposed modification, Petitioner includes two annotated versions of Aizawa’s Figure 1(b), both of which are reproduced below. Pet. 26.



Petitioner’s annotated figure on the left depicts Aizawa’s sensor with a “Cover with flat surface”; Petitioner’s annotated figure on the right depicts Aizawa’s sensor with a “Cover with protruding convex surface” (both illustrated with blue outline). Petitioner contends that, in the combination, the convex surface is above the wall provided by the holder and between the tissue of the user and the photodiodes. Pet. 49 (citing, e.g., Ex. 1003 ¶ 114)

Petitioner also identifies Japanese Patent Application 2006-296564 to Inokawa (Ex. 1007 (Japanese language); Ex. 1008 (English language translation)), which Petitioner contends “provides an additional motivation and rationale . . . to modify Aizawa to include a cover comprising a protruding convex surface.” Pet. 27. According to Petitioner, Inokawa teaches a convex lens that “increase[s] the light-gathering ability of the LED.” *Id.* (citing Ex. 1008 ¶ 15, Fig. 2. Petitioner contends that, in view of

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Inokawa, a person of ordinary skill in the art would have understood how to implement Ohsaki's convex surface in Aizawa. *Id.* at 27–28 (citing Ex. 1003 ¶¶ 82–84).

Patent Owner's Arguments

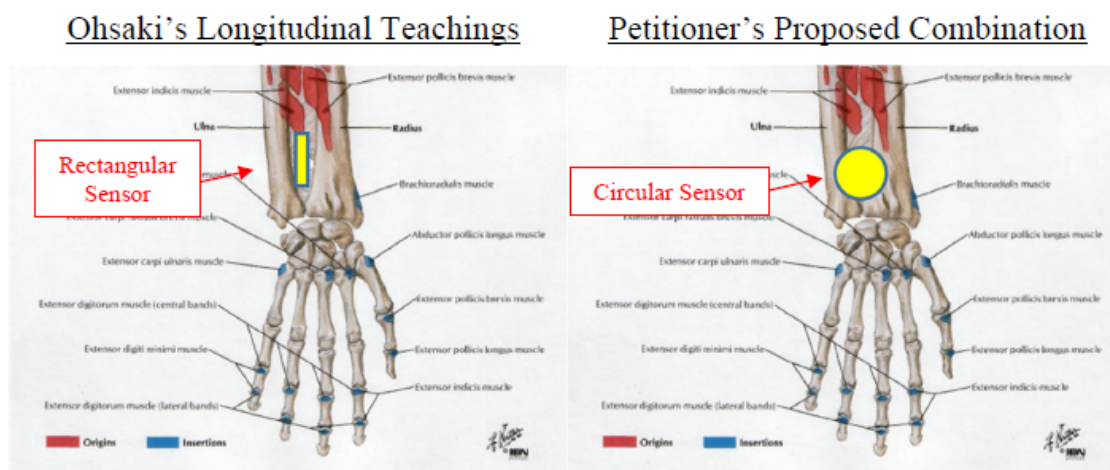
Patent Owner argues that a person of ordinary skill in the art would not have been motivated to modify Aizawa's sensor to include Ohsaki's convex cover. PO Resp. 21–53;⁵ PO Sur-reply 3–22.

First, Patent Owner argues that the proposed modification “fundamentally changes Ohsaki's structure and eliminates the longitudinal shape that gives Ohsaki's translucent board the ability to prevent slipping.” PO Resp. 23. This argument is premised on Patent Owner's contention that Ohsaki's convex cover must be rectangular, with the cover's long direction aligned with the length of the user's forearm, to avoid interacting with bones in the wrist and forearm. *Id.* at 23–26 (citing, e.g., Ex. 2004 ¶¶ 53–57; Ex. 1014 ¶¶ 6, 19, 23, 24). According to Patent Owner, Ohsaki teaches that “aligning the sensor's longitudinal direction with the circumferential

⁵ As an initial matter, Patent Owner observes that Petitioner “[r]eli[es] on a non-ground reference, Inokawa,” as providing the rationale for the proposed modification of Aizawa in view of Ohsaki, and as providing implementation details of the combination. RO Resp. 22 (citing Pet. 28); *id.* at 44–45, 50–53. We discern no error in Petitioner's identification of Inokawa. The nature of Petitioner's reliance on Inokawa in support of this ground is explained clearly in the Petition, even if Inokawa is not listed as an additional reference in the identification of the ground. Thus, the Petition complies with 35 U.S.C. § 312(a)(3) (stating an IPR petition must “identif[y], in writing and with particularity . . . the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge”).

direction of the user's arm undesirably results in 'a tendency [for Ohsaki's sensor] to slip off.'" *Id.* at 25–26 (citing Ex. 1014 ¶ 19).

Thus, Patent Owner contends that Petitioner's proposed modification would "chang[e] Ohsaki's longitudinal detecting element and rectangular board into a circular shape[, which] would eliminate the advantages discussed above" because a circular shape "cannot be placed in *any longitudinal* direction and thus cannot coincide with the longitudinal direction of the user's wrist." *Id.* at 26 (citing Ex. 2004 ¶¶ 57–58). Patent Owner presents annotated Figures depicting what it contends is Ohsaki's disclosed sensor placement as compared to that of the proposed modification, reproduced below. *Id.* at 27.



Patent Owner's annotated Figure on the left depicts a rectangular sensor placed between a user's radius and ulna, while Patent Owner's annotated Figure on the right depicts a circular sensor placed across a user's radius and ulna. Based on these annotations, Patent Owner argues that the proposed "circular shape would press on the user's arm in all directions and thus cannot avoid the undesirable interaction with the user's bone structure," such that a skilled artisan would have understood such a change would eliminate

Ohsaki's benefit of preventing slipping. *Id.* at 29 (citing, e.g., Ex. 2004 ¶¶ 57–58), 29 (citing Ex. 2004 ¶¶ 55–62).⁶

Second, Patent Owner argues that Ohsaki requires its sensor be placed on the back of the user's wrist to achieve any benefits, but that such a location would have been unsuitable for Aizawa's sensor. PO Resp. 32. Specifically, Patent Owner argues that Aizawa's sensor must be worn on the palm side of the wrist, close to radial and ulnar arteries, which is the side opposite from where Ohsaki's sensor is worn. *Id.* at 32–38 (citing, e.g., Ex. 2004 ¶¶ 67–74). According to Patent Owner, Ohsaki teaches that the sensor's convex surface has a tendency to slip when placed on the palm side of the wrist, i.e., in the location taught by Aizawa. *Id.* at 38–41 (citing, e.g., Ex. 1014 ¶¶ 19, 23, 24; Ex. 2004 ¶¶ 75–81). Thus, Patent Owner argues that a person of ordinary skill in the art “would not have been motivated to use Ohsaki's longitudinal board—designed to be worn on the **back side** of a user's wrist—with Aizawa's **palm-side** sensor.” *Id.* at 41. Similarly, Patent Owner argues that Aizawa teaches away from the proposed modification because Aizawa teaches that its flat acrylic plate improves adhesion on the palm side of the wrist, while Ohsaki teaches that its convex board “has a tendency to slip” on the palm side of the wrist. *Id.* at 41–44 (citing, e.g., Ex. 2004 ¶¶ 82–85).

⁶ Patent Owner further argues, “[t]o the extent Petitioner contends a [person of ordinary skill in the art] would use Ohsaki's rectangular board on Aizawa's circular sensor . . . this argument is unsupported and incorrect.” PO Resp. 30. We do not read the Petition as making such a contention. We understand Petitioner to propose, in essence, changing Aizawa's circular *flat* cover into a circular *convex* cover. *See, e.g.*, Pet. 25.

Third, Patent Owner argues that a person of ordinary skill in the art would not have placed Ohsaki's convex cover over Aizawa's peripheral detectors because the convex cover would condense light toward the center and away from Aizawa's detectors, which would decrease signal strength. PO Resp. 44–52 (citing, e.g., Ex. 2004 ¶¶ 86–97). Patent Owner also contends that Petitioner and Dr. Kenny admitted as much in a related proceeding. *Id.* at 45–46 (citing, e.g., Ex. 2019, 45; Ex. 2020, 69–70). Patent Owner also relies on Figure 14B of the '195 patent to support its position. *Id.* at 46–47 (citing Ex. 1001, 36:3–6, 36:13–15). Additionally, Patent Owner argues that its position is also supported by Inokawa, which also uses a convex lens to direct light toward the center but, in Inokawa's structure, the light is directed from peripheral emitters toward a central detector. *Id.* at 50–52 (citing, e.g., Ex. 1008 ¶¶ 15, 58). In light of the foregoing, Patent Owner argues that a person of ordinary skill in the art would have understood that the proposed modification would have decreased signal strength by directing light away from Aizawa's peripheral detectors. *Id.* at 52.

Fourth and finally, Patent Owner argues that a person of ordinary skill in the art “would have understood that Aizawa's *flat* plate would provide better protection than a convex surface” because it “would be less prone to scratches.” *Id.* at 52–53 (citing Ex. 1008 ¶ 106; Ex. 2004 ¶¶ 98–99).

Petitioner's Reply

Concerning Patent Owner's first and second arguments, Petitioner responds that Ohsaki does not disclose the shape of its protrusion, other than its convexity as shown in Figures 1 and 2, nor does Ohsaki require a rectangular shape or placement on the back of the wrist in order to achieve

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the disclosed benefits. Pet. Reply 13–20 (citing, e.g., Ex. 1060 ¶¶ 18–30). Moreover, Petitioner asserts that “[e]ven if Ohsaki’s translucent board 8 were understood to be rectangular, obviousness does not require ‘bodily incorporation’ of features from one reference into another”; rather, a person of ordinary skill in the art “would have been fully capable of modifying Aizawa to feature a light permeable protruding convex cover to obtain the benefits” taught by Ohsaki. *Id.* at 16 (citing, e.g., Ex. 1060 ¶ 23). Similarly, regarding the location of the sensor, Petitioner asserts,

[E]ven assuming for the sake of argument that a [person of ordinary skill in the art] would have understood Aizawa’s sensor as being limited to placement on the backside of the wrist, and would have understood Ohsaki’s sensor’s “tendency to slip” when arranged on the front side as informing consideration of Ohsaki’s teachings with respect to Aizawa, that **would have further motivated** the [person of ordinary skill in the art] to implement a light permeable convex cover in Aizawa’s sensor, to improve detection efficiency of that sensor when placed on the palm side.

Id. at 18 (citing, e.g., Ex. 1060 ¶ 27). In other words, Ohsaki’s disclosure that a convex surface suppresses variation in reflected light would have motivated an artisan to add such a surface to Aizawa to improve detection efficiency of that sensor when placed on the palm side. *Id.* at 18–20.

Moreover, Petitioner replies that the proposed convex surface “would provide an additional adhesive effect that would reduce the tendency of that plate to slip, since it is well-understood that physically digging into the skin with a protrusion provides an additional adhesive effect.” *Id.* at 20 (citing Ex. 1060 ¶ 30).

Concerning Patent Owner’s third argument, Petitioner responds that Patent Owner’s argument about a convex cover directing light to the center

is belied by Ohsaki itself, which uses a convex cover over a non-centrally located detector. *Id.* (citing Ex. 1060 ¶ 31); *id.* at 30–31. According to Petitioner, Ohsaki demonstrates that even if a convex cover decreased signal strength (which it disputes), the additional benefit of reduced slippage would have been recognized by a skilled artisan. *Id.*

Further, Petitioner responds that adding a convex cover to Aizawa’s sensor would not decrease signal strength but, instead, “would improve Aizawa’s signal-to-noise ratio by causing more light backscattered from tissue to strike Aizawa’s photodetectors than would have with a flat cover” because such a cover improves light concentration across the entire lens and does not direct it only towards the center. Pet. 21–22 (citing, e.g., Ex. 1060 ¶¶ 31–34).

Petitioner asserts that Patent Owner and Dr. Madisetti “ignore[] the well-known optical principle of reversibility,” by which “a ray going from P to S will trace the same route as one from S to P” such that “rays that are not completely absorbed by user tissue will propagate in a reversible manner.” Pet. Reply 23 (quoting Ex. 1061, 92; citing, e.g., Ex. 1061, 87–92; Ex. 1062, 106–111; Ex. 1060 ¶ 35). When applied to Aizawa’s sensor, Petitioner contends that any condensing benefit achieved by a convex cover would thus direct emitted light toward Aizawa’s peripheral detectors. *Id.* at 23–25 (citing, e.g., Ex. 1060 ¶¶ 35–45). Petitioner explains that this principle of reversibility is recognized in Aizawa. *Id.* at 25 (citing, e.g., Ex. 1060 ¶¶ 41–44; citing Ex. 1006 ¶ 33).

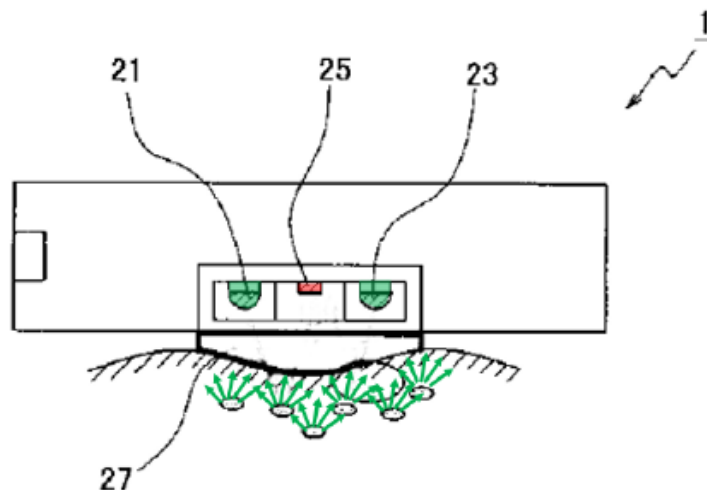
Petitioner also asserts that Patent Owner and Dr. Madisetti overlook the fact that light rays reflected by body tissue will be scattered and diffuse and will approach the detectors “from various random directions and

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angles.” Pet. Reply 25–27 (citing, e.g., Ex. 1023, 52, 86, 90; Ex. 1056, 803; Ex. 1060 ¶¶ 46–49; Ex. 2006, 163:12–164:2). This scattered and diffuse light, according to Petitioner, means that Ohsaki’s convex cover cannot focus light to the center of the sensor device, as Patent Owner argues. *Id.* at 26. Instead, due to the random nature of this scattered light, Petitioner asserts that a person of ordinary skill in the art would have understood that “Ohsaki’s convex cover provides a slight refracting effect, such that light rays that otherwise would have missed the detection area are instead directed toward that area as they pass through the interface provided by the cover.” *Id.* at 30 (citing, e.g., Ex. 1060 ¶¶ 48–49). Petitioner applies this understanding to Aizawa, and asserts that using a cover with a convex protrusion in Aizawa would “enable backscattered light to be detected within a circular active detection area surrounding” a central light source. *Id.* at 26.

Petitioner relies upon the following illustration of this alleged effect. Pet. Reply 29–30 (citing Ex. 1060 ¶¶ 54–55).



APPLE-1061, 141 (annotated)

The above illustration depicts backscattered light reflecting off user tissue and toward a convex board from various angles. *Id.* at 29. According to Petitioner, “[t]his pattern of incoming light cannot be focused by a convex lens towards any single location,” and, instead, “light rays that otherwise would have missed the active detection area are instead directed toward that area” as they pass through the interface provided by the convex cover. *Id.* at 29–30.

Finally, Petitioner dismisses Patent Owner’s reliance on Figure 14B of the ’195 patent because it “is not a representation of light that has been reflected from a tissue measurement site. The light rays (1420) shown in FIG. 14B are collimated (i.e., parallel to one another), and each light ray’s path is perpendicular to the detecting surface.” Pet. Reply 27–29 (citing, e.g., Ex. 1060 ¶¶ 51–53).

Concerning Patent Owner’s fourth argument, Petitioner responds that even if a flat surface might be less prone to scratching, that possible disadvantage would have been weighed against the “known advantages of applying Ohsaki’s teachings,” and would not negate a motivation to combine. *Id.* at 32 (citing, e.g., Ex. 1060 ¶ 60). Moreover, Petitioner argues that “by choosing a suitable material of the protrusion to be scratch-resistant, [] it would have been obvious for a [person of ordinary skill in the art] to achieve both benefits (light gathering and scratch-resistance) at once.” *Id.*

Patent Owner’s Sur-reply

Concerning Patent Owner’s first and second arguments, Patent Owner reiterates its position that Ohsaki’s purported benefits attach only to a sensor with a rectangular convex surface that is located on the back of the wrist,

and that “even small changes in its sensor’s orientation or body location result in ‘a tendency to slip.’” PO Sur-reply 3–14, 6.

Concerning Patent Owner’s third argument, Patent Owner asserts that Petitioner’s Reply improperly presents several new theories as compared with the Petition. *Id.* at 16 (regarding reversibility), 19 (regarding refraction).

Patent Owner argues that Dr. Kenny and Petitioner have not overcome their admissions that a convex lens directs light toward the center. *Id.* at 15. Moreover, Patent Owner argues that Petitioner’s discussion of the principle of reversibility is “irrelevant” because “Petitioner never explains how the principle of reversibility could apply to such ‘random’ scattered and absorbed light” as is present when light interacts with user tissue. *Id.* at 16. The random nature of backscattered light, in Patent Owner’s view, “hardly supports Petitioner’s argument that light will necessarily travel the same paths regardless of whether the LEDs and detectors are reversed,” and is irrelevant to the central issue presented here of “whether changing Aizawa’s flat surface to a convex surface results in more light on Aizawa’s peripherally located detectors.” *Id.* at 17.

Patent Owner also asserts that Petitioner mischaracterizes Patent Owner’s position, which is not that a cover with a convex protrusion “focuses **all** light to a single point” at the center of the sensor as Petitioner characterizes it. PO Sur-reply 19. Patent Owner’s position, rather, is that Petitioner has not shown that a person of ordinary skill in the art “would have been motivated to change Aizawa’s flat surface to a convex surface to improve signal strength.” *Id.* In Patent Owner’s view, by arguing that the convex cover provides only a “slight refracting effect,” Petitioner

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undermines its contention that providing such a cover would have improved detection efficiency. *Id.*

Moreover, Patent Owner argues that Petitioner’s theory regarding the “slight refracting effect” of a convex protrusion is “unavailing because it fails to consider the greater *decrease* in light at the detectors due to light redirection to a *more* central location.” *Id.* According to Patent Owner, any light redirected from the sensor’s edge could not make up for the loss of signal strength from light redirected away from the detectors and toward the center. *Id.* at 20.

Concerning Patent Owner’s fourth argument, Patent Owner argues that Petitioner does not dispute Patent Owner’s position that a flat cover would be less prone to scratches and offers “*no* plausible advantages for its asserted combination.” *Id.* at 22. Moreover, Patent Owner argues that “the risk of scratches undermines Petitioner’s argument that a [person of ordinary skill in the art] would have been motivated to add a convex cover to ‘protect the elements within the sensor housing.’” *Id.*

Analysis

As noted above, Petitioner provides three rationales to support its contention that a person of ordinary skill in the art would have modified Aizawa’s flat cover to include a protruding convex surface, such as that taught by Ohsaki, to (1) improve adhesion between the sensor and the user’s tissue, (2) improve detection efficiency, and (3) protect the elements within the sensor housing. Pet. 24–25. We conclude all three rationales are supported by the evidence, as follows.

Rationales 1 and 2

The evidence of record persuades us that adding a single protruding convex surface, such as that taught by Ohsaki, to Aizawa's cover would have improved adhesion between the sensor and the user's skin, which would have increased the signal strength of the sensor. Ohsaki teaches as much:

[T]he convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby *it is prevented that the detecting element 2 slips off* the detecting position of the user's wrist 4. If the translucent board 8 has a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4 as shown in Fig. 4B. However, in the case that the translucent board 8 has a convex surface like the present embodiment, the *variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed*. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8. Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

Ex. 1014 ¶ 25 (emphases added); *see also id.* ¶ 27 (“stably fixed”).

We credit Dr. Kenny's testimony that a person of ordinary skill in the art would have been motivated by such teachings to apply a cover with a convex surface to Aizawa to improve that similar device in the same way, i.e., to “simply improv[e] Aizawa-Mendelson-2003's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor.” *See, e.g.*, Ex. 1003 ¶ 81; *id.* ¶¶ 78 (“[T]his contact between the convex surface and the user's skin is said to prevent slippage, which increases the strength of the signals obtainable by Ohsaki's sensor.”), 78–79. We also credit Dr. Kenny's testimony that, in light of these teachings, a person of ordinary skill in the art would have

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made such a modification to improve the pulse sensor's ability to emit light into, and detect light reflected from, the user's wrist, to generate an improved pulse signal. Ex. 1003 ¶¶ 77–81; Ex. 1060 ¶¶ 11–13, 29.

Indeed, Ohsaki expressly compares the performance of a wrist-worn pulse wave sensor depending on whether translucent board 8 is convex or flat, and concludes the convex surface results in improved performance over the flat surface, especially when the user is moving. Ex. 1014, Figs. 4A–4B, ¶¶ 15, 25 (stating that with “a flat surface, the detected pulse wave is adversely affected by the movement of the user's wrist 4,” and with “a convex surface like the present embodiment, the variation of the amount of the reflected light” collected by the sensor “is suppressed”). Ohsaki also states that, with a convex surface, “[i]t is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8.” *Id.* ¶ 25.

We also credit Dr. Kenny's testimony that the proposed modification would have been within the skill level of an ordinary artisan. For example, Dr. Kenny testifies:

[A person of ordinary skill in the art] would have combined the teachings of Aizawa-Mendelson-2003 and Ohsaki as doing so would have amounted to nothing more than the use of a known technique to improve similar devices in the same way. For instance, a [person of ordinary skill in the art] would have recognized that incorporating Ohsaki's convex surface is simply improving Aizawa-Mendelson-2003's transparent plate 6 that has a flat surface to improve adhesion to a subject's skin and reduce variation in the signals detected by the sensor. Furthermore, the elements of the combined system would each perform similar functions they had been known to perform prior to the combination. That is, Aizawa-Mendelson-2003's transparent plate 6 would remain in the same position,

performing the same function, but with a convex surface as taught by Ohsaki.

Ex. 1003 ¶ 81. In light of Ohsaki’s express disclosure of the benefits of a convex cover, we credit Dr. Kenny’s testimony that a person of ordinary skill in the art would have been motivated to modify Aizawa as proposed, and would have had a reasonable expectation of success in doing so.

We next address Patent Owner’s first through third arguments, each of which implicates Petitioner’s first and second asserted rationales of improved adhesion and detection efficiency.

Patent Owner’s first argument is premised on the notion that Ohsaki’s benefits only can be realized with a rectangular convex surface, because such a shape is required to avoid interacting with bones on the back of the user’s forearm. PO Resp. 23–32. We disagree. Ohsaki does not disclose the shape of its convex cover, much less require it be rectangular. In fact, Ohsaki is silent as to the shape of the convex surface. Ohsaki discloses that sensor 1 includes detecting element 2, which includes package 5 within which the sensor components are located. Ex. 1014 ¶ 17. Ohsaki’s convex surface is located on board 8, which is “attached to the opening of the package 5.” *Id.* Ohsaki provides no further discussion regarding the shape of board 8 or its convex protrusion.

We disagree with Patent Owner’s suggestion that the shape of the convex surface can be inferred to be rectangular from Ohsaki’s Figures 1 and 2. PO Resp. 17–18. Ohsaki does not indicate that these figures are drawn to scale, or reflect precise dimensions or shapes of the convex surface. *See, e.g.*, Ex. 1014 ¶ 13 (“schematic diagram”); Pet. Reply 14–15; *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000) (“[I]t is well established that patent drawings do not define the

precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.”).

To be clear, Ohsaki describes the shape of *detecting element 2* as rectangular: “[T]he length of the detecting element 2 from the right side to the left side in FIG. 2 is longer than the length from the upper side to the lower side.” Ex. 1014 ¶ 19. Ohsaki also describes that detecting element 2 is aligned longitudinally with the user’s forearm: “[I]t is desirable that the detecting element 2 is arranged so that its longitudinal direction agrees with the longitudinal direction of the user’s arm,” to avoid slipping off. *Id.*; see also *id.* ¶ 9 (“The light emitting element and the light receiving element are arranged in the longitudinal direction of the user’s arm.”).

In light of this disclosed rectangular shape of detecting element 2, it is certainly possible that Ohsaki’s convex surface may be similarly shaped. But, it may not be. Contrary to Patent Owner’s argument, Ohsaki neither describes nor requires detecting element 2 to have the same shape as the convex surface of board 8. *Accord* Pet. Reply. 13–14. We have considered the testimony of both Dr. Kenny and Dr. Madisetti on this point. Ex. 1060 ¶¶ 10, 12, 18–23; Ex. 2004 ¶¶ 36–39 (relying on Ohsaki’s Figures 1–2 to support the opinion that the convex surface is rectangular). Dr. Madisetti’s reliance on the dimensions of Ohsaki’s figures is unpersuasive. *Hockerson-Halberstadt*, 222 F.3d at 956. We credit Dr. Kenny’s testimony that Ohsaki does not describe its convex surface as rectangular, because this testimony is most consistent with Ohsaki’s disclosure.

Further, Patent Owner suggests that the convex surface *must be* rectangular, in order to avoid interacting with bones in the user’s forearm. PO Resp. 24–26; PO Sur-reply 10 (“[A] POSITA would have understood

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Ohsaki's convex board must *also* have a longitudinal shape oriented up-and-down the watch-side of the user's wrist/forearm."). Although Ohsaki recognizes that interaction with these bones can cause problems, (*see* Ex. 1014 ¶¶ 6, 19), we do not agree that the *only way* to avoid these bones is by aligning a rectangular cover with the longitudinal direction of the user's forearm. For example, in the annotated Figures provided by Patent Owner, *see* PO Resp. 27, we discern that the circular sensor that purports to depict the proposed modification would *also* avoid the bones in the forearm if it were slightly smaller. Patent Owner provides no persuasive explanation to justify the dimensions it provides in this annotated figure, or to demonstrate that such a large sensor would have been required. Indeed, we discern that it would have been within the level of skill of an ordinary artisan to appropriately size a modified sensor to avoid these well-known anatomical obstacles. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. After all, an artisan must be presumed to know something about the art apart from what the references disclose. *See In re Jacoby*, 309 F.2d at 516.

Finally, we do not agree with Patent Owner's position that Ohsaki's advantages apply only to rectangular convex surfaces. As discussed, Patent Owner has not shown that Ohsaki's convex surface is rectangular at all. Moreover, even if Ohsaki's convex surface is rectangular, when discussing the benefits associated with a convex cover, Ohsaki does not limit those benefits to a cover of any particular shape. Instead, Ohsaki explains that "detecting element 2 is arranged on the user's wrist 4 so that the convex surface of the translucent board 8 is in intimate contact with the surface of the user's skin. Thereby it is prevented that the detecting element 2 slips off

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the detecting position of the user's wrist 4." Ex. 1014 ¶ 25; Ex. 1060 ¶¶ 10 ("Ohsaki does not limit its benefits to a rectangular sensor applied to a particular body location, and a [person of ordinary skill in the art] would not have understood those benefits as being so limited."), 12. Thus, we agree with Petitioner that Ohsaki's teaching of a convex surface would have motivated a person of ordinary skill in the art to add such a surface to Aizawa's circular-shaped sensor, to improve adhesion as taught by Ohsaki. Nothing in Ohsaki's disclosure limits such a benefit to a specific shape of the convex surface. Ex. 1060 ¶¶ 10–23.

Moreover, Ohsaki contrasts the ability to properly receive reflected light with a convex surface as compared to a flat surface and notes that,

in the case that the translucent board 8 has a convex surface . . . the variation of the amount of the reflected light which is emitted from the light emitting element 6 and reaches the light receiving element 7 by being reflected by the surface of the user's skin is suppressed. It is also prevented that noise such as disturbance light from the outside penetrates the translucent board 8. Therefore the pulse wave can be detected without being affected by the movement of the user's wrist 4 as shown in FIG. 4A.

Ex. 1014 ¶ 25; Ex. 1060 ¶¶ 12–13. Again, we agree with Petitioner that Ohsaki's teaching of a convex surface would have motivated a person of ordinary skill in the art to add such a surface to Aizawa's sensor, to improve signal strength, as taught by Ohsaki. Again, nothing in Ohsaki's disclosure limits such a benefit to the shape of the convex surface.

Accordingly, we do not agree that Ohsaki's disclosed advantages attach only to a rectangular convex surface, or would have been inapplicable to the proposed combination of Aizawa and Ohsaki.

We have considered Patent Owner's second argument, that Ohsaki's benefits are realized only when the sensor and convex surface are placed on

the back of the user's wrist, which is the opposite side of the wrist taught by Aizawa. PO Resp. 32–44. We do not agree. As an initial matter, Petitioner does not propose bodily incorporating the references; Petitioner simply proposes adding a convex cover to Aizawa's sensor, without discussing where Aizawa's sensor is used. *See, e.g.*, Pet. 25. In other words, Petitioner's proposed modification does not dictate any particular placement, whether on the palm side or back side of the wrist.

To be sure, Ohsaki's Figures 3A–3B compare the performance of detecting element 2, including its translucent board 8 having a convex protrusion, and show better performance when the element is attached to the back side of the wrist versus the front side of the wrist, when the user is in motion. *See* Ex. 1014 ¶¶ 23–24, Figs. 3A–3B. However, we do not agree that these figures support Dr. Madiseti's conclusion that “Ohsaki indicates a convex surface only prevents slipping on the back (i.e., watch) side of the wrist in a specific orientation, but tends to slip when used in different locations or orientations” such as the palm side of the wrist—particularly in comparison to a flat surface such as Aizawa's. Ex. 2004 ¶¶ 67–81. Instead, Ohsaki acknowledges that, even when the detecting element is located “on the front [palm] side of the user's wrist 4, *the pulse wave can be detected well* if the user is at rest.” Ex. 1014 ¶ 23 (emphasis added). Thus, Ohsaki discloses that, in at least some circumstances, a convex surface located on the front of the user's wrist achieves benefits. *Id.* Notably, the claims are not limited to detection during movement or exercise.

We credit, instead, Dr. Kenny's testimony that a person of ordinary skill in the art would have understood from Ohsaki that a convex protrusion will help prevent slippage, even in the context of Aizawa's sensor. *See*

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Ex. 1060 ¶¶ 10–11, 15–16, 24–30. Dr. Kenny acknowledges that “certain locations present anatomical features that provide for easy measurement of large reflected light signals and other locations present anatomical features that reduce the amplitude of the reflected light signals. Because of this, a [person of ordinary skill in the art] would be motivated to search for features from other references that can provide improved adhesion, improved light gathering, reduced leakage of light from external sources, and protection of the elements within the system in order to successfully detect a pulse wave signal from many locations.” *Id.* ¶ 16. We credit Dr. Kenny’s testimony that, in light of Ohsaki’s teaching of a convex protrusion in “intimate contact with the surface of the user’s skin,” a skilled artisan would have understood that such a surface “would have increased adhesion and reduced slippage of Aizawa’s sensor when placed on either side of a user’s wrist or forearm, and additionally would have provided associated improvements in signal quality.” *Id.* ¶ 29.

Dr. Madisetti testifies that “[b]ased on Aizawa’s teaching that a flat acrylic plate improves adhesion on the palm side of the wrist, and Ohsaki’s teaching that a convex surface tends to slip on the palm side of the wrist, a [person of ordinary skill in the art] would have come to the opposite conclusion from Dr. Kenny: that modifying Aizawa’s [flat adhesive plate] ‘to include a lens/protrusion . . . similar to Ohsaki’s translucent board 8’ would not ‘improve adhesion.’” Ex. 2004 ¶ 85. We disagree with this reading of Aizawa. It is true that Aizawa’s plate 6 is illustrated as having a flat surface (Ex. 1006, Fig. 1(b)), and that Aizawa states the plate “improve[s] adhesion” (*id.* ¶ 13). Aizawa further states: “the above belt 7 is fastened such that the acrylic transparent plate 6 becomes close to the

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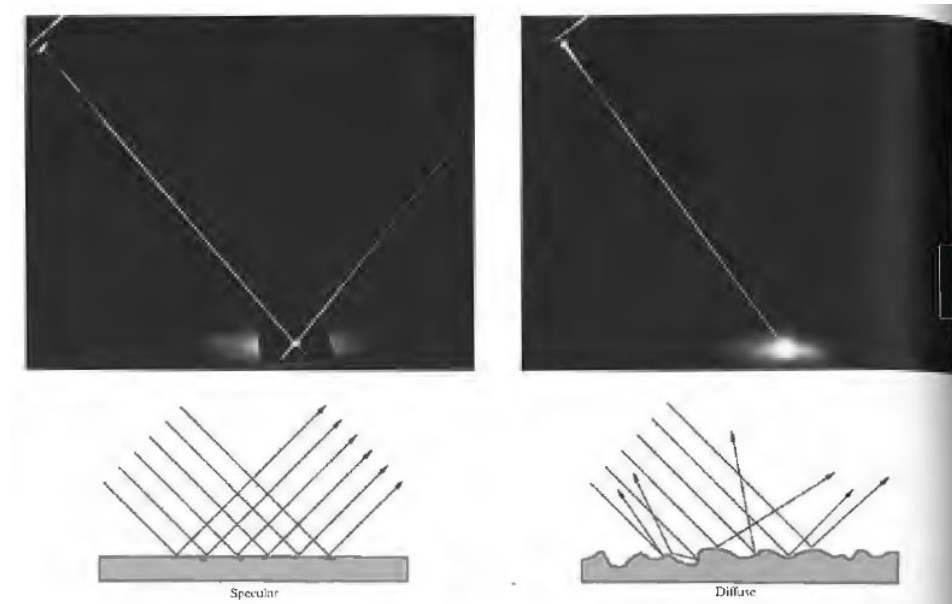
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artery 11 of the wrist 10,” and “[t]hereby, adhesion between the wrist 10 and the pulse rate detector 1 is improved.” *Id.* ¶ 26. These disclosures, however, indicate the improved adhesion is provided by the acrylic material of plate 6, not the shape of the surface of the plate, which is never specifically addressed. *Id.* ¶¶ 30, 34 (“Since the acrylic transparent plate 6 is provided . . . adhesion between the pulse rate detector 1 and the wrist 10 can be improved . . .”). Aizawa does not associate this benefit of improved adhesion with the surface shape of the plate, but rather, with the existence of an acrylic plate to begin with. Thus, there is no teaching away from using a convex surface to improve the adhesion of Aizawa’s detector to the user’s wrist.

We have considered Patent Owner’s third argument that a convex cover would condense light away from Aizawa’s peripheral detectors, which Patent Owner alleges would decrease signal strength. PO Resp. 44–52. We disagree.

There appears to be no dispute that when emitted light passes through user tissue, the light diffuses and scatters as it travels. *See, e.g.,* Pet. Reply 25 (“[R]eflectance-type sensors work by detecting light that has been ‘partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.’ A [person of ordinary skill in the art] would have understood that light that backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles.”) (quoting Ex. 1023, 86); PO Sur-reply 16–17 (“Petitioner admits that tissue randomly scatters and absorbs light rays, which would cause forward and reverse light paths to be unpredictable and very likely different.”).

The light thus travels at random angles and directions, and no longer travels in a collimated and perpendicular manner. Exhibit 1061,⁷ Figure 4.12, illustrates the difference between diffuse and collimated light, and is reproduced below:



This figure provides at left a photograph and an illustration showing incoming collimated light reflecting from a smooth surface, and at right a photograph and an illustration of incoming collimated light reflecting from a rough surface. See Ex. 1061, 87–88 (original page numbers). The smooth surface provides specular reflection, in which the reflected light rays are collimated like the incoming light rays. See *id.* The rough surface provides diffuse reflection, in which the reflected light rays travel in random directions. See *id.*; see also Ex. 1060 ¶¶ 38–39 (discussing Ex. 1061, Figure 4.12), 46 (“A [person of ordinary skill in the art] would have understood that light that backscatters from the measurement site after

⁷ Eugene Hecht, *Optics* (2nd ed. 1990).

diffusing through tissue reaches the active detection area from many random directions and angles.”).

Dr. Kenny testifies that Aizawa’s sensor “detect[s] light that has been ‘partially reflected, transmitted, absorbed, and scattered by the skin and other tissues and the blood before it reaches the detector.’” Ex. 1060 ¶ 53 (quoting Ex. 1023, 86). Dr. Kenny further opines that a convex cover, when added to Aizawa’s sensor with multiple detectors symmetrically arranged about a central light source, allows “light rays that may have otherwise missed the detection area [to be] instead be directed toward that area as they pass through the interface provided by the cover,” thus increasing the light-gathering ability of Aizawa’s sensor. *Id.* ¶ 49.

By contrast Dr. Madisetti testifies that “a convex ‘lens/protrusion’ would direct light away from the detectors and thus result in decreased light collection and optical signal strength at the peripheral detectors” because it condenses light towards the center of the sensor and away from the peripheral detectors. Ex. 2004 ¶¶ 86–87, 90. We have considered this testimony, however, Dr. Madisetti’s opinions largely are premised upon the behavior of collimated and perpendicular light as depicted in Figure 14B of the challenged patent. *See id.* ¶ 89. Dr. Madisetti does not explain how light would behave when approaching the sensor from various angles, as it would after being reflected by tissue. *Id.* ¶¶ 87–90; *see also id.* ¶¶ 91–97 (addressing motivation and also failing to discuss diffuse, scattered light). In other words, even if Patent Owner is correct that the ’195 patent’s Figure 14B depicts light condensing toward the center, this is not dispositive to the proposed modification, because light reflected by a user’s tissue is

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scattered and random, and is not collimated and perpendicular as shown in Figure 14B. Ex. 1001, Fig. 14B.

Patent Owner and Dr. Madisetti argue that “Petitioner and Dr. Kenny both [previously admitted] that a convex cover condenses light towards the center of the sensor and away from the periphery,” in a different petition filed against a related patent, i.e., in IPR2020-01520. PO Resp. 45–46; Ex. 2004 ¶ 87. The cited portions of the Petition and Dr. Kenny’s declaration from IPR2020-01520 discuss a decrease in the “mean path length” of a ray of light when it travels through a convex lens rather than through a flat surface. *See, e.g.*, Ex. 2020 ¶¶ 118–120. We do not agree that this discussion is inconsistent with Dr. Kenny’s testimony here that, where light is reflected to the detectors at various random angles and directions, more light will reach Aizawa’s symmetrically disposed detectors when travelling through the convex surface than would be reached without such a surface, because light that might have otherwise missed the detectors now will be captured. *See, e.g.*, Ex. 1060 ¶¶ 31 (“[A] cover featuring a convex protrusion would improve Aizawa’s signal-to- noise ratio by causing more light backscattered from tissue to strike Aizawa’s photodetectors than would have with a flat cover.”), 34 (“improves ‘light concentration at pretty much *all of the locations under the curvature of the lens*’”), 46 (“A [person of ordinary skill in the art] would have understood that light which backscatters from the measurement site after diffusing through tissue reaches the active detection area from various random directions and angles.”), 49 (“[L]ight rays that may have otherwise missed the detection area are instead directed toward that area as they pass through the interface provided by the cover.”); *see generally id.* ¶¶ 31–59. We do not discern that the convergence of a

single ray of light toward the center, as discussed in IPR2020-01520, speaks to the aggregate effect on *all* light that travels through the convex surface.

We additionally do not agree with Patent Owner's argument that Petitioner's Reply presents new theories that should have been first presented in the Petition, to afford Patent Owner an adequate opportunity to respond. The Petition proposed a specific modification of Aizawa to include a convex protrusion in the cover, for the purpose of, *inter alia*, increasing the light gathering ability of Aizawa's device. *See* Pet. 25. Patent Owner's Response then challenged that contention, with several arguments that Petitioner's proposed convex protrusion would not operate in the way the Petition alleges it would operate. *See* PO Resp. 44–52. This opened the door for Petitioner to provide, in the Reply, arguments and evidence attempting to rebut the contentions in the Patent Owner Response. *See* PTAB Consolidated Trial Practice Guide (Nov. 2019) (“Consolidated Guide”),⁸ 73 (“A party also may submit rebuttal evidence in support of its reply.”). This is what Petitioner did here. The Reply does not change Petitioner's theory for obviousness; rather, the Reply presents more argument and evidence in support of the same theory for obviousness presented in the Petition. *Compare* Pet. 22–28, *with* Reply 20–31.

Rationale 3

Petitioner further contends that a person of ordinary skill in the art would have recognized that a cover with a protruding convex surface, such as that taught by Ohsaki, would “protect the elements within the sensor housing” of Aizawa. Pet. 25. We are persuaded that adding a convex cover, such as that taught by Ohsaki, would also protect the sensor's internal

⁸ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

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components in a manner similar to Aizawa's flat acrylic plate. Ex. 1003 ¶ 80; Ex. 1060 ¶ 60; *see also* Ex. 1008 ¶ 15 (noting that a cover "protect[s] the LED or PD").

We disagree with Patent Owner's fourth argument that a person of ordinary skill in the art would not have modified Aizawa as proposed because a convex cover would be prone to scratches and because other alternatives existed. Patent Owner does not explain how the potential presence of scratches on a convex cover would preclude that cover's ability to, nonetheless, protect the internal sensor components in Aizawa, as Petitioner proposes. That a convex cover may be more prone to scratches than Aizawa's flat cover is one of numerous tradeoffs that a person of ordinary skill in the art would consider in determining whether the benefits of increased adhesion, signal strength, and protection outweigh the potential for a scratched cover. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Moreover, as Petitioner notes, and Patent Owner does not dispute, a scratch resistant material could be employed in fabricating the cover. Pet. Reply 32; PO Sur-reply 23. The record does not support the premise that the possibility of scratches alone would have dissuaded a person of ordinary skill in the art from the proposed modification, to achieve the benefits identified by Petitioner.

For the foregoing reasons, we are persuaded by Petitioner's contentions.

vi. "[i] wherein the physiological measurement device provides a plurality of optical paths, wherein each of the optical paths: [j] exits an emitter of the one or more emitters, [k] passes through tissue of the user, [l] passes through the single protruding convex surface, and [m] arrives at a corresponding photodiode of the at least one

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consistent with Aizawa's disclosure and Dr. Kenny's undisputed testimony. *See, e.g.*, Ex. 1006 ¶ 27 ("Near infrared radiation output toward the wrist 10 from the light emitting diode 21 is reflected by a red corpuscle running through the artery 11 of the wrist 10 and this reflected light is detected by the plurality of photodetectors 22 so as to detect a pulse wave (see FIG. 1(b)."), Fig. 1(b) (depicting two optical paths from emitter 21 to detectors 22 in Aizawa's sensor); Ex. 1003 ¶¶ 115–117.

vii. Summary

For the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claim 1 would have been obvious over the cited combination of references.

6. Dependent Claims 2–15

Petitioner contends that claims 2–15 would have been obvious based on the same combination of prior art addressed above. Claims 2–15 depend directly or indirectly from independent claim 1. Ex. 1001, 45:35–46:62.

i. Dependent Claims 2–8 and 10–14

Petitioner identifies teachings in the prior art references that teach or suggest the limitations of these claims, and provides persuasive reasoning as to why the claimed subject matter would have been obvious to one of ordinary skill in the art. Pet. 51–64, 66–81, 85. Petitioner also supports its contentions for these claims with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 118–135, 139–162, 184–186.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1.

PO Resp. 65 (“[T]he Petition fails to establish that independent claims 1 and 16 are obvious in view of the cited references of Ground 1 and therefore fails to establish obviousness of any of the challenged dependent claims.”); *see supra* § II.D.5.

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that 2–8 and 10–14 would have been obvious over the combined teachings of the cited references and as supported by the testimony of Dr. Kenny.

ii. Dependent Claims 9 and 15

Dependent claim 9 ultimately depends from independent claim 1 and further recites the “protruding convex surface protrudes a height between 1 millimeter and 3 millimeters.” Ex. 1001, 46:14–16.

Dependent claim 15 ultimately depends from independent claim 1 and further recites the “protruding convex surface protrudes a height greater than 2 millimeters and less than 3 millimeters.” *Id.* at 46:59–62.

Petitioner contends that the sensor rendered obvious by the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Goldsmith would have included a cover with a protruding convex surface. *See supra* § II.D.5.v. With respect to claim 9, Petitioner contends that a person of ordinary skill in the art “would have found it obvious that a device designed to fit on a user’s wrist would be on the order of millimeters,” consistent with Ohsaki’s disclosure that the device is in “intimate contact” with the user’s skin. Pet. 64–65 (citing, e.g., Ex. 1003 ¶¶ 136–137). Petitioner also contends that an ordinarily skilled artisan would have taken user comfort into account when establishing the dimensions of the device’s convex cover. *Id.* With

these considerations in mind, Petitioner contends that, “in order to provide a comfortable cover that prevents slippage, the convex surface should protrude a height between 1 millimeter and 3 millimeters,” because “there would have been a finite range of possible protruding heights, and it would have been obvious to select a protruding height that would have been comfortable to the user.” *Id.* at 66 (citing, e.g., Ex. 1003 ¶ 138). With respect to claim 15, Petitioner incorporates its contentions regarding claim 9. Pet. 81; Ex. 1003 ¶ 163

Patent Owner argues that none of the cited references discloses the claimed height range and that Petitioner relies on hindsight reconstruction. PO Resp. 66 (citing, e.g., Ex. 2004 ¶¶ 120–125). Patent Owner also characterizes Dr. Kenny’s testimony as conclusory and unsupported. *Id.* at 68–69.

Petitioner is correct that, when “there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product . . . of ordinary skill and common sense.” *KSR*, 550 U.S. at 402. Petitioner has shown sufficiently that only a finite number of solutions existed with respect to the height of a convex protrusion on a tissue-facing sensor, which would have met the art-recognized goals of both (1) intimate contact between the sensor’s surface and the user and (2) user comfort. *See, e.g.*, Ex. 1014 ¶¶ 6, 25. Bearing in mind these considerations, we credit Dr. Kenny’s testimony that it would have been obvious, “in order to provide a comfortable cover featuring a protruding convex surface that prevents slippage, [that] the

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surface should protrude a height between 1 millimeter and 3 millimeters,” as recited in claim 13, and which further includes the claimed range of 2 to 3 millimeters as recited in claim 17. Ex. 1003 ¶ 138. Further, the record does not support that any new and unexpected results were achieved at the claimed height greater than 2 millimeters and less than 3 millimeters. *See, e.g.*, Ex. 1001, 23:43–50 (“The height 430 can be from about 0.5 millimeters to about 3 millimeters, e.g., about 2 millimeters. In an embodiment, the dimensions 400, 410, and 430 can be selected such that the measurement site contact area 470 includes an area of about 80 square millimeters, although larger and smaller areas can be used for different sized tissue for an adult, an adolescent, or infant, or for other considerations.”).

We have considered Patent Owner’s argument, and Dr. Madisetti’s cited testimony. However, it is not dispositive that none of the cited references teaches the claimed range. PO Resp. 66; Ex. 2004 ¶ 121. Petitioner relies upon the knowledge, ability, and creativity of a person of ordinary skill in the art, not the teachings of a specific reference. Notably, Dr. Madisetti does not dispute Dr. Kenny’s position that there were a finite number of options available for the height of the convex surface. Ex. 2004 ¶¶ 121–125. Therefore, we do not agree that Petitioner’s contentions are rooted in impermissible hindsight. *See, e.g., In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) (“Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.”).

Accordingly, for the foregoing reasons, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 9 and 15 would have been obvious over the cited combination of references.

7. *Claims 16 and 17*

Independent claim 16 includes limitations [a]–[h] and includes additional limitations drawn to “a plurality of windows,” “preprocessing electronics,” “one or more processors,” a “network interface,” a “touch-screen display,” and “storage device,” a “strap,” and “a plurality of optical paths.” Ex. 1001 46:63–48:39. Dependent claim 17 depends directly from claim 16 and further recites a “handheld computing device” *Id.* at 48:40–44.

In asserting that claim 16 would have been obvious over the combined teachings of Aizawa, Mendelson-2003, Ohsaki, and Goldsmith, Petitioner refers to the contentions made regarding claim 1, as well as claims depending therefrom. *See* Pet. 81–84. Regarding claim 17, Petitioner refers to the contentions made regarding, *inter alia*, claim 10. *Id.* at 86. Petitioner also supports its contentions for these claims with the testimony of Dr. Kenny. Ex. 1003 ¶¶ 164–186.

Patent Owner does not present any arguments for these claims other than those we have already considered with respect to independent claim 1. PO Resp. 11–65 (addressing claims 1 and 16 together with respect to Petitioner’s first ground and stating, “the Petition fails to establish that independent claims 1 and 16 are obvious in view of the cited references of Ground 1 and therefore fails to establish obviousness of any of the challenged dependent claims”); *see supra* § II.D.5.

For the same reasons discussed above, we determine that Petitioner has met its burden of demonstrating by a preponderance of the evidence that claims 16 and 17 would have been obvious over the cited combination of references. *See supra* II.D.5; Ex. 1003 ¶¶ 164–186.

*E. Obviousness over the Combined Teachings of
Aizawa, Mendelson-2003, Ohsaki, Goldsmith, and Ali*

Petitioner provides arguments and evidence, including the Kenny Declaration, in support of Petitioner’s additional ground challenging claims 1–17 of the ’195 patent. Pet. 86–89; Ex. 1003 ¶¶ 187–191. Because we have already determined that those claims are unpatentable based on Aizawa, Mendelson-2003, Ohsaki, and Goldsmith, which is dispositive as to all challenged claims, we need not reach this additional ground. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (“[T]he Board need not address issues that are not necessary to the resolution of the proceeding.”).

III. CONCLUSION

In summary, we determine that a preponderance of the evidence establishes claims 1–17 of the '195 patent are unpatentable, as shown in the following table:⁹

Claim(s)	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–17	103	Aizawa, Mendelson-2003, Ohsaki, Goldsmith	1–17	
1–17	103 ¹⁰	Aizawa, Mendelson-2003, Ohsaki, Goldsmith, Ali		
Overall Outcome			1–17	

⁹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

¹⁰ As explained above in Section II.E, because we conclude that claims 1–17 are unpatentable on other grounds, we do not reach the merits of this ground.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–17 of the '195 patent have been shown to be unpatentable; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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